

3D printed obturators - An innovative journey

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ABSTRACT

The children suffering from cleft palate undergo physical and psychological trauma of a basic life function of feeding until the surgeon deems it suitable for corrective surgery. It is highly discouraging for the parents to face the ordeal being suffered by the child. Over the years, several modalities have been developed in the form of techniques and products to improve the feeding experience of the child. However, all of these products come with a certain set of problems including the difficulty of fabrication, cost, availability, etc. This article covers the journey of the D-cleft from the clinical trials of various designs and prototypes and improvement of the disadvantages of these finally leading to a device, which is easy to use, flexible, biocompatible, affordable, and customisable.

Keywords: 3D printing machine, Complete, D-cleft, denture, feeder, feeding plate, obturator, stereolithography

Introduction

The formation of congenital cleft palate may be majorly attributed to the failure of palatal shelves at the embryonic stage. This has been observed in a number of syndromes such as the Pierre Robin syndrome. It is a huge physical and psychological compromise for the infant and not a very motivating sight for the parents of the child to see them going through the discomfort of a basic life function such as feeding on a daily basis. This may be mainly because of the tongue, which is unable to make a seal with the palate, and thus, due to no intraoral pressure being formed, the chances of the fluid going into the cleft increase more.

Case History

A number of devices are used for aiding the children suffering from the practical problems associated with cleft palate such

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as Pigeon nipple with one way valve, Haberman Feeder, Mead Johnson, Soft squeeze bottle with tubing, etc. [Figure 1].

Keeping in mind, all the modalities and treatment protocols for children suffering from cleft palate and the associated disadvantages, a device was attempted to be fabricated, which would serve the purpose of obturating without the inherent disadvantages of the above-mentioned methods or devices. The procedure started with the impression making of the child, who was more willing for the procedure, although with an apprehension, keeping in mind, the problems associated with impression making [Figure 2]. A cast was poured and an obturator plate was made which instead of inserting in the defect was attached to the lid of the bottle. It was named the "Feeding Plate Attachment" [Figure 3].

The Feeding Plate Attachment was used during the feeding of the patients. The mechanism of action involved the device being attached to the bottle lid that would cover the cleft and the fluid would be unable to pass through the cleft, thus facilitating the fluid going through the intended path [Figure 4]. This device

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Figure 1: Pigeon nipple with one-way valve, Haberman Feeder, Mead Johnson, Soft squeeze bottle with tubing



Figure 2: Impression making for Feeding Plate Attachment



Figure 3: Feeding Plate Attachment



Figure 4: Child being fed through the device

has all the advantages of the obturator without any obvious disadvantages. This was how the journey of the D-cleft device started.

The journey of the D-cleft started with an acrylic spoon being attached to the feeding bottle rim [Figure 5]. It was very effective in reducing the flow of the liquid into the cleft and was much more compatible than a conventional obturator in terms of comfort in deglutition. However, it had disadvantages, such as brittleness leading to frequent breakage and in turn, trauma to the soft and hard tissue anatomy as well as due to inflexibility, it was not able to adapt to the margins of the defect, and thus, caused discomfort.

The Feeding Plate Attachment when relined proved to be a better alternative to the acrylic spoon in terms of flexibility, adaptability and strength but due to the inherent requirement of impression making, it was not desirable.

To overcome these disadvantages, a device was visualised and an approximate copy of the same was made in modelling wax. This involved the circumference of a feeding bottle covered with a wax outline and a serpent head extension, which would cover the defect completely and may even cover beyond the margins of the defect [Figure 6].

The Flashforge 3D printing machine (Zhejiang Flashforge 3D Technology Co., Ltd., Zhejiang Province, China) was procured

and polylactic acid (PLA) was used for the fabrication of the D-cleft devices. The advantages of PLA are that it is easy to procure, economically viable and there is an easy availability of raw material such as sugarcane. It is biocompatible as it is used in the medical implant industry, female hygiene, diaper industry, and disposable garment industry.^[1]

A patent was filed and design modifications were done for the development of the D-cleft [Figure 7]. A computer-aided industrial design (CAID) software, i.e., the Autodesk Alias software was used in designing the D-cleft, which was later fabricated through 3D printing. The prototypes were made using the Flashforge 3D printing machine [Figure 8]. The D-cleft was made in such a way that in the same product, there were three sizes which were detachable as per the size of the cleft in question. The difference in the circumference between the biggest and smallest size was about 150% [Figure 9].

No studies have been done in the past, which could be used for preparing the D-cleft with certain dimensions. Thus, from the associated institutes, where these studies were going on, impressions were made and casts were poured from the children suffering from cleft palate visiting for treatments such as obturators/nasoalveolar moulding (NAM) or any other intervention, which were used to fabricate the D-cleft serpent head extensions.

Discussion

The challenges posed to the children and parents are innumerable, and the most important of them is that of nutrition. The inability



Figure 5: The acrylic spoon



Figure 6: Wax mock-up for the D-cleft

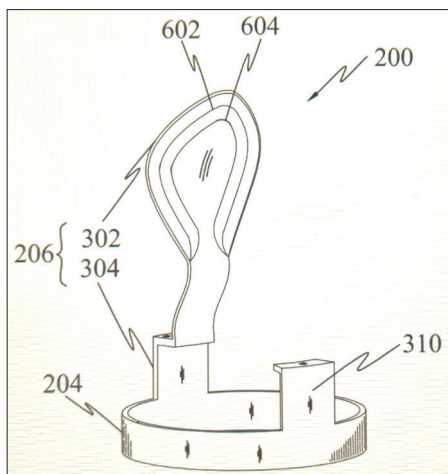


Figure 7: Original design for patent



Figure 8: Prototype of the D-cleft made from Flashforge 3D printing machine

of the tongue to form a seal with part or whole of the palate prevents the formation of negative intraoral pressure and in the absence of a positive seal, the swallowing process is compromised leading to a myriad of problems. To counter these, the child, the parent, and the dental surgeon forms a team under the speciality of Palliative Pedodontics.

The common feeding problems faced by the child are choking, inefficient suckling, prolonged feeding time, and nasal regurgitation. The entry of the food or fluid through the cleft and the inability of the palatal seal formation are the causative factors for the same.^[2]

The traditional feeding methods are the breast, the feeding bottle, the cup, and the spoon.^[3] However, in children suffering from cleft palate, the mother and child's feeding position needs to be altered or the design of the feeding bottle is to be modified so that gravity may play its part and the flow of milk/liquid in the cleft may be avoided. The modifications in the feeding positions include side-lying, cross-cradle and modified feeding hold position.^[4]

World-renowned companies associated with childcare products have introduced feeding bottles especially for children suffering

from cleft palate such as a Pigeon nipple with one-way valve, Haberman feeder, Mead Johnson and Soft squeeze bottle with tubing but these have their respective inherent problems such as leakage around the nipples, difficult sterilization, high cost and non-availability, respectively.^[5]

Another commonly used feeding modality is the nasogastric tubing to eliminate any chances of the food/fluid passing through the cleft. However, the disadvantages of the nasogastric tubing are the risk of perforation, internal injury or haemorrhage, stiffness with use, bacterial colonisation and loss of sucking reflex.^[6]

The obturator or nasoalveolar moulding is the most commonly used modality for covering the defect while feeding the child. However, factors such as cumbersome impression making may lead to a part of the impression material breaking and going into the defect causing havoc for the child, the doctor, and the caretaker. After fabrication, training the caretaker in terms of maintenance and sterilization, expensive manufacturing and repeated appointments for adjustment causes considerable inconvenience and cost.^[7]

3D printing has enabled the rapid, convenient, eco-friendly and pocket-friendly production of the D-cleft, one of the myriads of products that is being used for production today.^[8] In case, where the D-cleft with its specifications and size modifications does not suit the needs of the patient, there is a provision for scanning the

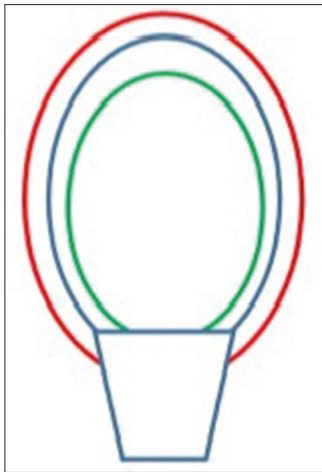


Figure 9: Size variations in D-cleft as per cleft requirements

palate and extending the scan in case of the cleft lip also, so that a customised product can be made for the patient. Apart from this, innovation is also going on, in case, the child is not accepting the bottle where the mother's breast can be scanned and the D-cleft made as per the specifications, so that the child may be able to suckle from the mother than the bottle. With these developments and mass production, along with the provision of the D-cleft being an over-the-counter (OTC) product, it is being strived to make this product readily available and affordable for patients from the lower socioeconomic strata also. The Food and Drug Administration (FDA) approval is yet to be obtained which will open up more prospects for the D-cleft to be marketed in India and international markets and will be able to solve the feeding issues in children with cleft palate.

The benefits of the D-cleft in the real world are significant as it gives a completely comprehensive method of facilitating the feeding in children suffering from cleft palate who are either waiting for corrective surgery or inoperable due to various factors. It provides a great boost to the child and his/her parents physically and psychologically.^[9]

The most significant drawback of D-cleft is that it is in the nascent stages and exhaustive clinical trials need to take place over various sample sizes and issues including the age of the patient, extent of the cleft, etc. However, in the future, these issues can be addressed as and when they arise through newer techniques and materials.^[10]

Conclusion

An attempt has been made to provide a solution for the feeding problem inherent in children suffering from cleft palate. The conventionally available methods and techniques have certain sets of disadvantages such as difficulty in fabrication, technique

sensitive, risks of perforation and injury, lack of skilled specialists, frequent adjustments, training of parent/guardian, increased costs and a myriad of other problems and limitations.

The variations in the position for mother and child cause a lot of inconvenience for both. Conventionally available bottles for use in patients with cleft palate have certain disadvantages which affect one or more types of defects. The nasogastric tubing in the long-run has set disadvantages that may have irreversible effects for the child.

The D-cleft is an attempt to provide a simple, affordable, readily available and easily cleansable device that provides maximum comfort to the child and the basic life function of feeding can be achieved without any compromise.

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Conflicts of interest

There are no conflicts of interest.

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