CLINICAL CASE STUDY

Feasibility of three-dimensional nasal imaging and printing in producing customized nasal masks for non-invasive ventilation in extremely low birth weight infant: A pilot study

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Abstract

Several studies have been conducted to investigate the feasibility of customized nasal masks produced by three-dimensional (3D) facial imaging and printing for continuous positive airway pressure in adults and in premature mannequin. In addition to replicating the entire process, we applied the customized nasal mask to a premature patient who weighed less than 1,000 g. Facial scanning was performed. The study masks were manufactured using stereolithography with a 3D printer model Form3BL (FormLABS). Elastic 50 resin was used as the material. We verified the feasibility of the correct transmission of non-invasive ventilation and found that the mask improved the respiratory parameters and reduced the need for supplemental oxygen. The fraction of inspired oxygen (FiO₂) was lowered from 45%, which was the requirement when the traditional mask is used, to almost 21% when the nasal mask was applied to the premature patient, who was either in incubator or in kangaroo position. In view of these results, a clinical trial is being launched to evaluate the safety and efficacy of 3D-printed masks in extremely low birth weight (ELBW) infants. 3D printing provides an alternative for obtaining customized masks that may be more suitable for non-invasive ventilation in ELBW infants than traditional masks.

Keywords: Child health; Intensive care units; Neonatal; Neonatology; Technology and therapeutics

1. Introduction

Currently, most preterm infants are managed with non-invasive ventilation (NIV) in neonatal intensive care units. However, technical limitations of NIV are especially apparent in infants who weigh less than 1,000 g (extremely low birth weight, ELBW). The nasal masks available for use in NIV are often not adapted to the size and morphology of ELBW infants. This is an important limitation that leads to prolonged intubation or
continuous loss of pressure that favors pulmonary collapse in the infants.

Several studies have been conducted to investigate the feasibility of three-dimensional (3D) facial imaging and printing in producing customized nasal masks for continuous positive airway pressure in adults [1,2]. In the field of neonatology and pediatrics, there have been some publications regarding the models for maxillofacial, airway, and cardiovascular surgeries [3-7]. Of note, one of the most recent publications pertains to premature mannequin [8]. However, to date, we have not identified any studies on the production of customized nasal masks by 3D printing (the mask will be referred to as M3D thereafter) for use in NIV in ELBW infants. For this reason, we decided to conduct a pilot study to assess the feasibility of producing M3D for NIV in ELBW infants.

2. Methods

This study was approved by the Clinical Research Ethics Committee 22/288, Research Committee (TP/0086) and conducted with the approval and consent of the parents.

A portable pediatric 3D facial scanning system (AsorCad Engineering S.L.) with LED light was used to digitize the subject's facial geometry. This step necessitates the use of a device that does not need contact with the baby, can be used inside the incubator, and does not use harmful radiations. Pre-scanning tests were performed on a mannequin (Figure 1) and the surface in the process of designing the mask. Pressure transmission in the mannequin was tested by attaching the mask to the usual NIV device. In the mannequin used (Anne premature Laerdal®), airflow transmission was confirmed by auscultation, and the movement of the chest wall was also visualized.

Facial scanning was performed on a 45-day-old premature infant of 25 weeks' gestational age, who weighed 580 g (Figure 2). In order to perform the facial scanning, the NIV mask must be removed. The scanner has a good temporal resolution (in seconds and usually less than 1 minute). The scan needs to be repeated if the baby moves frequently.

The customized nasal masks were manufactured using stereolithography with a 3D printer model Form3BL (FormLABS). The material used was Elastic 50 resin, which is an elastic photopolymer with a Shore A 50 hardness that implies an elasticity at the most adequate level.

The printed nasal mask showed a perfect fit and allowed pressure transmission in NIV. The use of the M3D was compared to the use of a traditional mask (TM) in two different positions or settings. M3D were tested in incubator (Figure 3) for 2 hours and in kangaroo position for 2 hours. Usually, the premature infant was placed in kangaroo position when the parents were present. Data were recorded for 2 hours with TM and 2 hours with M3D.

Data were collected from both incubator and kangaroo position. Vital signs and NIV parameters as well as possible local skin lesions were recorded. No gasometric or carbon dioxide monitoring controls were performed due to clinical and respiratory stability.
3. Results

The fraction of inspired oxygen (FiO₂) was lowered from 45%, which was the requirement when TM is used, to almost 21% when M3D was applied to the premature infant, who was either in incubator or in kangaroo position (Figure 4). A decrease in mean pressure was also observed when the M3D was applied, indicates a better seal. Given the stability of the respiratory parameters, the nursing routinely decreased the peak inspiratory pressure level and positive end expiratory pressure on the NIV device and automatically adjusted the mean airway pressure level. The preterm infant did not manifest desaturations or bradycardias. When the M3D was removed, slight marks (Figure 5) were evident on the skin at the contact points in the nasal root. The appearance of mild perinasal red marks on the skin could be observed 100 minutes after the placement of M3D, but they subsided in the following hours and resolved at 24 hours.

4. Discussion

Elastic 50 resin from FormLabs is a softer engineering resin suitable for the manufacture of devices. It is normally made of silicone and has a Shore A 50 hardness.
It is classified as a medical resin, and its applications include the production of medical models and devices. The mask manufactured with this resin can be sterilized by superheated steam (autoclave sterilization) without altering its mechanical properties, as indicated by the manufacturer. To date, no studies have been carried out to prototype customized nasal mask using Elastic 50 resin. Thus, a short-duration test of 2 hours was required for close follow-up. In this pilot study, the M3D made a correct seal and improved the parameters of NIV but left behind mild perinasal red marks on the surface of the nasal root, which, fortunately, did not result in a skin lesion or allergic reaction.

In this first prototype, no cushion was added to the nasal mask. Although the wall is thin, the cushion, which is custom-made, fits well to the nasal surface of the premature infant, and it is not necessary to fix the M3D in the same way as with the TM.

It would be desirable for this resin to have a Shore A 18 to 20 hardness so that it has the properties of a silicone (i.e., softer and more flexible), which could help prevent the marking on the nasal cutaneous area of the premature infant while maintaining the correct transmission.

In this initial phase of the application of M3D, we observed that there was presumably better pressure transmission since the nasal seal was much better given that the mask was custom-made. Therefore, it was possible to reduce the oxygen supply required through NIV in the 2 hours when the infant subject was being tested.

Adjustments to the NIV, such as a decrease in supplemental oxygen concentration according to the infant's oxygen saturation, were necessary because the M3D had a better seal. Figure 4 shows the oxygen requirements both in the incubator and in the kangaroo position.

The only side effect was the transient mark described in the nasal root. Since the mask was put on for only 2 hours, observations and outcomes for longer duration are required for further validation. We will also need to identify the most suitable resin for fabrication. All newborns under 1,500 g should be routinely followed up after hospital discharge.

When M3D was replaced by TM, more supplemental oxygen was needed. One of the limitations of this study is that the data revolving around the supplemental oxygen upon the mask replacement were not recorded but were directly observed by the investigators. The parents requested that the application of M3D should be continued, but such request was not accommodated since this was the pilot phase of the study. Another limitation is that the M3D was tested on only one infant. In the clinical trial (PI21/00628) that will be carried out later, these data will be recorded.

The customized nasal mask fabricated by 3D printing in this study is a highly personalized mask for extremely small, premature newborns, and it offers better seal that allows for better transmission of pressure, thereby reducing the need for supplemental newborns. In contrast, TM does not usually fit well to the premature nasal region; therefore, it is generally less effective in NIV.

The first prototype as reported in this study produced some marks in the nasal root of the infant; however, we anticipate improvement in this regard when new materials are to be utilized in the clinical trial, which is currently underway.

5. Conclusion
A clinical trial has been launched to evaluate the safety and efficacy of the customized nasal masks in ELBW infants. 3D printing opens up a new field for fabricating items for ELBW children.

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Conflict of interest
All authors declare no conflicts of interests.

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**Ethics approval and consent to participate**
This study was approved by the Clinical Research Ethics Committee 22/288, Research Committee (TP/0086) and conducted with the approval and consent of the parents.

**Consent for publication**
Both written and verbal consent has been obtained from the parents of the premature infant to publish the infant's data and images.

**Availability of data**
The data was collected in an excel document and in the patient's electronic health record. Data can be made available upon reasonable request.

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