Neonatal Nasal CPAP Device Redesign

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Introduction

Continuous Positive Airway Pressure (CPAP) is primarily indicated for use in treating respiratory distress. CPAP was adapted for infants in the 1970’s as an alternative to the more invasive mechanical ventilation. Its primary function is to establish an open airway. The circuit is structured such that a continuous flow of humidified oxygen in combination with other compressed gases is delivered. The gases usually meet with the infant at the nasal area\(^1\). The entire circuit for nasal Continuous Positive Airway Pressure (nCPAP) is shown in Figure 1\(^6\).

CPAP is accomplished by a variety of methods. In one of these, nasopharyngeal prongs that span from the nares to the nasopharynx are used. Due to their long length, the airway resistance is higher when compared to other methods. Additionally, they are difficult to insert. The most popular method offered by EME Medical, Inc utilizes either nasal prongs or a mask\(^1\). Both nosepieces are shown in Figure 2\(^6\). The nasal prongs consist of short dual prongs that rest at the base of the nose. The mask covers only...
the nose. The CPAP goal is accomplished by supplying 4-8 cmH₂O positive airway pressure into the infant’s airway².

The nasal CPAP circuit manufactured by EME Medical includes three tubes; one each for intake, outtake and measuring the supplied pressure. The outtake tube also serves the purpose of noise reduction. The tubes converge at the nosepiece that hovers above the nose. The entire apparatus is secured in place with a bonnet². An infant is shown attached to the device in Figure 3. Premature infants are especially prone to respiratory distress syndrome and other forms of pulmonary disease. This is due to their lack of physiological development as a result of premature birth⁷.

CPAP use varies widely from institution to institution. Each hospital adopts unique protocols for determining the implementation of

Table 1: CPAP administration classified by weight at Columbia University (A) and by year at two different hospitals (B).¹

<table>
<thead>
<tr>
<th>Weight (g)</th>
<th>CPAP (%)</th>
<th>CPAP %*</th>
<th>CPAP/IMV (%)</th>
<th>CPAP/IMV %*</th>
<th>Expired</th>
</tr>
</thead>
<tbody>
<tr>
<td>1251–1820</td>
<td>128</td>
<td>(83%)</td>
<td>25</td>
<td>(17%)</td>
<td>(7%)</td>
</tr>
<tr>
<td>1001–1250</td>
<td>63</td>
<td>(70%)</td>
<td>26</td>
<td>(53%)</td>
<td>(9%)</td>
</tr>
<tr>
<td>751–1000</td>
<td>47</td>
<td>(47%)</td>
<td>27</td>
<td>(53%)</td>
<td>(9%)</td>
</tr>
<tr>
<td>501–750</td>
<td>20</td>
<td>(26%)</td>
<td>57</td>
<td>(74%)</td>
<td>(34%)</td>
</tr>
</tbody>
</table>

*% of infants managed with CPAP or CPAP and ventilation.

<table>
<thead>
<tr>
<th></th>
<th>Children’s Hospital of New York</th>
<th>Vermont Oxford</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasal CPAP</td>
<td>87</td>
<td>88</td>
</tr>
<tr>
<td>Conventional ventilation</td>
<td>42</td>
<td>40</td>
</tr>
<tr>
<td>High frequency ventilation</td>
<td>16</td>
<td>6</td>
</tr>
<tr>
<td>Surfactant</td>
<td>27</td>
<td>19</td>
</tr>
<tr>
<td>Steroids for CLD</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>Oxygen &gt;50 weeks</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Died</td>
<td>10</td>
<td>14</td>
</tr>
</tbody>
</table>
CPAP. However, at Columbia University, approximately 62% of all infants under 1500g of weight were treated with nasal CPAP. A more detailed dissection of nasal CPAP use by weight during a two-year period from 1999-2001 appears in Table 1. In comparison, Table 2 also details the respiratory care for infants weighing less than 1500g at two other hospitals. At the Children’s Hospital of New York, on average, nasal CPAP was used on approximately 88% of the infants under 1500g and on approximately 52% of the infants at Vermont Oxford. It is not uncommon for infants to be treated using a combination of methods, hence the sum of percentages greater than 100% for each year.

**Alternative Respiratory Care Methods**

Several other methods are available for the treatment of respiratory complications in infants. The advantages and disadvantages of some common methods are detailed in Table 2. Additionally, some other previously dismissed methods, like the head box and Bloxsom Air Lock, have been reexamined to determine if they are still applicable for modern use. The head box was one of the first methods used to administer continuous positive airway pressure. It functioned by enclosing the infant’s head within a box to maintain the positive pressure. However, its practice was largely abandoned upon the introduction of nasal CPAP\(^1\). The Bloxsom Air Lock functioned similarly to the head box. It supplied humidified positive pressure consisting of 60% oxygen. However, when tested in clinical trials, the device failed to provide evidence of efficacy\(^4\).
Nasal CPAP remains the least invasive and one of the most easily administered respiratory treatment methods. In contrast, intubation is extremely invasive and can cause secondary problems in association with its use. While the head box and Bloxsom Air Lock methods are also easily administered, they restrict access to the infants that are often in need of additional intensive care, which is especially problematic when resuscitation is required\textsuperscript{1}. Ultimately, the physician determines the choice after thorough consideration of the needs of the infant.
Problem

Nasal CPAP has been linked to nasal injuries and deformities as a consequence of prolonged use. According to interviews with nurses and physicians at Vanderbilt University Children’s Hospital, each nosepiece type is implicated in characteristically different injuries. Vanderbilt currently employs the use of the Infant Flow Driver manufactured by EME Medical, which features two nosepiece types: a nasal mask and nasal prongs. The prongs and mask are both associated with septal erosion. This is shown in Figure 4A. Additionally, the mask also leads to nasal bridge contusions\(^2\). Robertson et al also reported nasal flaring and snubbing as a result of prolonged nasal prong use. Evidence of nasal snubbing as a result of prolonged prong use is shown in Figure 4B\(^5\).

Figure 4: Injuries sustained from extended CPAP use. Septal erosion (A) and nasal snubbing after 60 days of CPAP (B).
Objectives

The main objective of this project was to analyze the applied force of the device on the nasal area. From this, conclusions concerning the cause of the specific injuries could be more clearly discerned. After analyzing the forces, a new design could then be proposed to accommodate the forces in an attempt to remedy the nasal complications. Additionally, the present designs as well as potential future designs have to be used correctly in order to accomplish the goal without sacrificing the patient's wellbeing. By making nurses and physicians aware of the potential complications and their respective causes, future injuries would likely be prevented.
Methods

Interviews

Since this is the first year this project has been offered, we had a lot of ground to cover. We began our search in the literature, as discussed in the previous section, and in the NICU itself. We interviewed some nurses and doctors about the various problems with this device. We wanted to get a firsthand view on what they thought caused the injury and how they tried to remedy the problems.

Dr. Walsh provided us with information about the injury. After a week on the device, the nurses keep a close eye out for injury. It takes about two weeks for a minor injury to form. The longer the infant is on this system, the worse the injury gets. The infants get breaks from the device in the form of nasal cannula or intubation depending on how much they depend on CPAP. The smaller the infant, the longer they are on CPAP and more they need it. The smaller infants usually start on intubation and then move to CPAP.

The nurses were very helpful. They also said they start to look out for injury after a week. They said that the prongs cause more nasal flaring than any other injury, and the mask cause more septal injury. Since the nosepieces cause different injury, the nurses switch the infants between the mask and the prongs to help prolong the occurrence of injury. The infants take time off of the device as much as possible, which is not very often for most. To help remedy the septal injury problem, the nurses try to cushion the nosepiece with some adhesive
bandages. This seems to help prolong the time to injury, but does not prevent nasal flaring.

**Testing Procedure**

We are using EME (Electro Medical Equipment) Ltd. Infant Flow™ nCPAP System. This system includes a Generator, three prong sizes (small, medium, large), two mask sizes (extra-small, extra-large), nine bonnet sizes, and the delivery circuit (tubing for the in flux of air, pressure sensor, out flux of air). This is hooked up to the Aladin system driver, which monitors the air flow and pressure going to the device\(^6\). Testing was done in the NICU.

To test the injury findings from the interviews and literature, we obtained an infant CPR doll to make a cast of its face. From this cast, we used a soft modeling clay and a dental amalgam type material to make a testable model of the face. We hooked these models up to the complete circuit (Figure 5). We learned that the nurses tighten the device until the proper pressure of 4 to 8cm H2O. This requires quite a bit of tightening. We used a clay model to test both the prongs and the mask. We also tested the amalgam.
Limitations

We ran into a few problems in the testing process. We wanted to have the most realistic skin model we could find. However, there is limited literature on the nature of a neonate’s skin. Some of the infants on this device don’t have a fully formed epidermis yet. This created a major problem since we could not find anything written about Young’s Modulus of neonate skin. Dr. Walsh said that the best model is wet tissue or modeling clay. We talked to Dr. Roselli about finding a model. He told us to find Young’s Modulus for the skin of an older child and divide it by 4 or so. He said he did not think that we would be able to find a number. We used clay because it deformed easily and quickly.

We would have liked to have a pressure sensor in the nostril and on the septum to measure the pressure exerted by the device on the nasal area. We could not find a device small enough or sensitive enough to measure the pressure accurately. Since our models were very soft materials, we could not get a very accurate pressure measurement unless we used an infant for testing. The device would not have worked on the clay and the amalgam was not as accommodating as actual skin.
Results

designsafe Report

The main safety risks associated with this device are the injuries we are trying to resolve. Some of these injuries are caused by human factors associated with placing the device on the infants face. The complete report of safety hazards is in Appendix B. The majority of these concerns are mild or easily remedied. The injury concerns are discussed throughout this report.

Testing Results

We found that the amalgam was not a good material to use. It did not deform easily. They clay deformed very well and is shown in Figure 6. We saw the nasal flaring and some septal damage with use with the prongs. The mask showed major septal deformation and some bridge damage. This is consistent with the injury the nurses found and the literature pointed out. The clay was an excellent material to use since it deformed quickly and accurately.

During testing, we found that none of the nosepieces fit the model face well at all. The model was a medium in prongs and an extra-large in the mask. There are only 3 prong sizes and two mask sizes. The medium prong was the
“best fit” compared to the other sizes, though it didn’t fit well. The prongs are closer together than the nostril of the model’s nose. The mask was enormous and fit over the nose and then some. Due to the poor sizing, it was difficult to maintain the pressure seal without really tightening the device to the face. The tightening process caused more flaring and mask injury than the device being used normally. The device does not need to be very tight to work effectively, but when the nosepiece does not fit well, it requires more pulling to get a seal.

We also noticed that the exhalation tube was very heavy and caused the device to tip, breaking the seal. The tube can be adjusted to prevent tipping by adjusting the bonnet strap that holds it. This cannot be done until the device is on properly. This can result in over tightening to maintain the seal before the tube can be adjusted. The tipping adds to the injuries already caused by the nosepiece. It also adds a lot of weight to the device. The adjustment of this tube along with tightening can be done simultaneously with two people. This can prevent over tightening of the device, but is inconvenient for the nurses.

**Marketing and Economics**

This device is currently on the market. The demand is relatively high in the neonatal segment. There are few competitors, but many alternatives, such as naso-pharengal tubes and intubation. The complete circuit costs about $120 USD per patient\(^9\). There are cheaper alternatives on the market, but the advantages of this device outweigh the cost.
Conclusions and Recommendations

Some basic guidelines for CPAP administration are suggested below for optimal nasal CPAP use while minimizing potential for injury. They are grouped into two categories according to the target audience: “Suggestions to Nurses and Physicians” and “Future Design Considerations”. These two lists are necessary since we did not finish all of our objectives. We did not have enough time to complete thorough testing and redesign of this device.

Suggestions to Nurses and Physicians

- **Ensure the nosepiece size is correct.** EME Medical provides a sizing chart to aid in selecting the appropriate size.
- **Ensure bonnet size is correct.** S.J. Foster, Managing Director of EME Ltd. emphasizes that an incorrect size may contribute to injury⁸.
- **Avoid overly tightening at the nasal interface as method of maintaining the proper airway pressure.** This may cause the nosepiece to tilt, leading to injury. Instead, try moving the bonnet on the infant’s head or repositioning the exhalation tube.
- **Training may be beneficial in making certain the above precautions are taken.**

Future Design Considerations

- **Increase the range in nosepiece sizes.** Currently, the size range is very limited, leading to being forced to choose between a size that is
Potentially too small or too large. A larger mask seems to be the most urgent nosepiece size that is not available.

- **Reduce weight of the generator.** Its bulkiness and weight appear to be large contributors to the tilting of the device, one of the large contributors of injury. This can be accomplished by using a lighter biomaterial or by eliminating the exhalation tubing completely. Yet, the new device should still incorporate noise reduction techniques to maintain the infant’s comfort.

- **Choose a stiffer biomaterial for the areas of the nosepiece that are not in contact with the nose.** This will improve the rigidity of the device and therefore prevent not only tilting but also movement and rotation at the nasal interface, which causes a break in the seal.

- **Explore other methods of anchoring the nosepiece to the infant.** The current bonnet method leads to the aforementioned tilting phenomenon. However, keep in mind safeguards to prevent suffocation.

- **Consider a different biomaterial for the entire nosepiece.**

- **Longer prongs may be beneficial in the bi-nasal prong design.** This would more securely anchor the nosepiece and eliminate the need to over tighten the nosepiece. This would also reduce the amount of tapering necessary on the prong to create a good seal. However, it is important to keep in mind the increased chance of irritation within the nares.
**Ethics**

There are a few ethical considerations to consider for the testing and ultimate design of this device. First we must consider the pressure testing of this device on infants. This could be done with the consent of the parents as long as a sterile pressure-sensing device was used to measure the pressure exerted by a device already in use on one of the infants. This would allow the most accurate pressure findings, since most models for an infant’s delicate skin are either too tough or too weak. Some people may not want to test on infants, but this would cause no harm and could be done without disturbing the infant too much.

Next, we must consider the biomaterials to be used in future designs. These must be on the FDA’s approved list of materials safe for use on humans. If a completely new device is made, it must undergo FDA approval for medical devices. Finding infant test subjects for testing may be difficult. Parents may not approve of the testing of a new device since the infants that require this device are either very sick or very small and delicate. Thorough animal testing would have to be done. This device could be tested on adults or older children first to ensure the new device works properly and does not cause injury.
References


2. William Walsh, M.D. Personal interview.


Appendix A

Ideation Process

Innovation Situation Questionnaire

1. Brief description of the problem
Weight and pressure of the CPAP apparatus causes ulcers on the infants nose.

2. Information about the system

2.1 System name
CPAP Apparatus

2.2 System structure
Nose fitting fits in or around nose.
Tube for exhaled air goes over top of head.
Device Velcroed to bonnet.
Inhaled air tube attached underneath the device.
Pressure sensing tube attached underneath.

2.3 Functioning of the system
A constant positive air pressure of around 6 cm H2O is maintained in the apparatus to keep the airway open.

2.4 System environment
Neonatal Intensive Care Unit
Air through the device at a constant temperature and humidity.

3. Information about the problem situation

3.1 Problem that should be resolved
Reduce force placed on the face either by redesign (weight reduction) or a cushioning added to minimize discomfort.
3.2 Mechanism causing the problem

Device is too heavy for an infant’s delicate skin.

3.3 Undesired consequences of unresolved problem

Open wounds can lead to infection.

3.4 History of the problem

Other generations of the device have been made. The current device reduced ulceration, but not by reducing weight and bulkiness.

3.5 Other systems in which a similar problem exists

Similar problems can be seen in adult used CPAP if used for a prolonged period of time.

3.6 Other problems to be solved

1. Reduce the weight.
2. Redesign nose fitting.
3. Use of softer (gel?) materials.

4. Ideal vision of solution

The device is light enough to not cause irritation, but still bulky enough to support air pressure.

5. Available resources

Device itself
Infant Model
CPAP machine
Air Source
Load sensor

6. Allowable changes to the system

1. Completely changing the device is allowed.
2. Added cushioning to device.
7. Criteria for selecting solution concepts

- Ease of use.
- Tight seal.
- Injury reduction.
- Low cost.

8. Company business environment

Over 400,000 infants require this device annually.

9. Project data

Infant CPAP Breathing Apparatus Design

Objective: Reduce injury to nasal area.

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Andrea Holland

e-mail: cpapvugroup14@yahoo.com

Problem Formulation

1. Build the Diagram
2. Directions for Innovation

» 1. Find a way to eliminate, reduce, or prevent [the] (Injury to nose) under the conditions of [the] (Pressure around nasal area).

2. Find an alternative way to obtain [the] (Device keeps constant pressure) that offers the following: provides or enhances [the] (Airway remains open), does not cause [the] (Pressure around nasal area).

3. Try to resolve the following contradiction: The useful factor [the] (Device keeps constant pressure) should be in place in order to provide or enhance [the] (Airway remains open), and should not exist in order to avoid [the] (Pressure around nasal area).

4. Find an alternative way to obtain [the] (Helps baby breathe) that does not require [the] (Airway remains open).

5. Consider transitioning to the next generation of the system that will provide [the] (Helps baby breathe) in a more effective way and/or will be free of existing problems.

6. Find an alternative way to obtain [the] (Airway remains open) that offers the following: provides or enhances [the] (Helps baby breathe), does not require [the] (Device keeps constant pressure).

7. Find a way to eliminate, reduce, or prevent [the] (Pressure around nasal area) in order to avoid [the] (Injury to nose), under the conditions of [the] (Device keeps constant pressure).

Prioritize Directions

1. Directions selected for further consideration

1. Find a way to eliminate, reduce, or prevent [the] (Injury to nose) under the conditions of [the] (Pressure around nasal area).

   1.1. Isolate the system or its part from the harmful effect of [the] (Injury to nose).

   1.2. Counteract the harmful effect of [the] (Injury to nose).

   1.3. Impact on the harmful action of [the] (Injury to nose).

   1.4. Reduce sensitivity of the system or its part to the harmful effect of [the] (Injury to nose).

   1.5. Eliminate the cause of the undesired action of [the] (Injury to nose).

   1.6. Reduce the harmful results produced by [the] (Injury to nose).

   1.7. Apply universal Operators to reduce the undesired factor (Injury to nose).

   1.8. Consider resources to reduce the undesired factor (Injury to nose).
1.9. Try to benefit from the undesired factor (Injury to nose).

2. **List and categorize all preliminary ideas**

Develop a cushion.

Use a softer biomaterial.

Create a lighter device.

Alternate way to support the device.

---

**Develop Concepts**

1. **Combine ideas into Concepts**

Develop a more cushioned surface that touches the skin.

The new device should weight substantially less than the previous design.

It could also be supported in areas besides the nose, like the cheeks.

2. **Apply Lines of Evolution to further improve Concepts**

This surface would need to be light-weight or have an alternative means of support to distribute the weight. A cushion would also help to lessen the load on the nose.

---

**Evaluate Results**

1. **Meet criteria for evaluating Concepts**

It would be difficult to construct a new device with our currently available materials.

We are also constrained by time. The next group would likely be able to implement these ideas into a prototype.

It would be helpful to sketch or model a new prototype.

Also, the pressure "hot-spots" should be kept in mind when redistributing the pressure.

Analyze biomaterials for weight reduction and increased cushioning.

Analyze other companies’ designs besides EME.

Use stiffer material in nosepiece except for the parts touching the nose.

---

2. **Reveal and prevent potential failures**
New problems can be introduced that were not present previously.

Different types of injury not seen by the current device.

Limited by reasonable costs.

3. Plan the implementation

Construct testable prototype nosepieces.

Numerous tests on different nosepiece designs to determine which puts the least amount of pressure on the nasal area.

Lessen the weight by reducing the thickness of the Generator.

Place holes for tubing elsewhere.

Try different tubing.
Appendix B

Nasal CPAP designsafe Report

Application: Nasal CPAP
Description: Analysis of nasal CPAP nasal interface
Analyst Name(s): Andrea Holland
Limits: specified by task and user
Sources: literature and past user experiences

Guide sentence: When doing [task], the [user] could be injured by the [hazard] due to the [failure mode].

<table>
<thead>
<tr>
<th>Task Risk Reduction Methods</th>
<th>User / Exposure</th>
<th>Initial Assessment</th>
<th>Final Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Severity</td>
<td>Hazard / Probability</td>
</tr>
<tr>
<td>skilled user normal use</td>
<td>mechanical : entanglement</td>
<td>MinimalOccasion</td>
<td>Moderate</td>
</tr>
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<td>On-going [Daily]nurses</td>
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<td></td>
<td></td>
</tr>
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<td>Complete</td>
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<tr>
<td>skilled user normal use TBDnurses</td>
<td>ergonomics / human factors : mental overload / underload</td>
<td>SeriousOccasion</td>
<td>High</td>
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<tr>
<td>TBDnurses</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>skilled user normal use TBDphysicians</td>
<td>ergonomics / human factors : human errors / behaviors</td>
<td>SeriousOccasion</td>
<td>High</td>
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<tr>
<td>skilled user normal use Complete</td>
<td>ventilation : airflow direction</td>
<td>SlightFrequent</td>
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<td>skilled user normal use Complete</td>
<td>pressure : low pressure</td>
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<td>High</td>
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