Non-invasive Ventilation and the VM-2000: Improving the Versatility of an Affordable, Easy-to-Use Emergency Ventilator

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Abstract

Ventis Medical is developing an affordable, easy-to-use emergency ventilator called the VM-2000 aimed at expanding accessibility of ventilator technology. The VM-2000 is intended to replace rudimentary bag-valve masks and existing transport ventilators, which are expensive, cumbersome, and complex. In this project, a mask attachment system and non-invasive ventilation (NIV) feature were developed for the VM-2000, expanding the versatility of the device by allowing it to be used without intubating the patient, a procedure that can be difficult to perform in emergency situations. First, a variety of existing respiratory masks were tested for the creation of a mask attachment. Second, an NIV mode developed by Ventis Medical was evaluated for its performance and used to test these masks. Third, an initial 3D model was built for a neck prop that could be used to help easily maintain an open airway in the patient during NIV. The VM-2000 is currently in the process of receiving FDA clearance, and in the future this NIV feature will be incorporated into the device and its operation to create a safer, more effective, and easier alternative to prior methods of ventilation.

Keywords: Emergency, Non-invasive ventilation (NIV), Mechanical ventilator, Ventis Medical, VM-2000

Introduction

Mechanical Ventilation

Mechanical ventilators are machines that support a patient's breathing by repeatedly blowing air into a patient's lungs and then allowing it to release when they are unable to do so on their own. These devices are a critical piece of lifesaving medical equipment, but the current standard of care in the intensive care unit (ICU) utilizes large and very complex ventilators that require management from a specially trained and certified respiratory therapist or someone who has demonstrated the same degree of competency and training[1]. Additionally, these ventilators are very expensive and are only built for stationary bedside care, which limits their use to the hospital room.

When a patient goes into respiratory failure and needs help outside of the ICU, is in a hard-to-reach location, is aboard an ambulance or rescue helicopter, or needs to be transported out of the ICU to another section of the hospital, the most common ventilation method is usually a bag valve mask. Bag valve masks, while affordable and simple to use, are rudimentary and unreliable devices. They require constant manual operation, demanding the full attention of the care provider that could be utilized elsewhere, and do not have the sensors or automated aspect of mechanical ventilation that allows for constant monitoring and provision of care for the patient.

These manual masks also leave significant room for human error that can put the patient at risk of lung injury, choking, or inadvertent ventilation of the stomach. Ventilator-induced lung injury (VILI) is an unfortunate but not uncommon problem when using these devices, primarily caused by excess stress on the aerated lung. An automated device can much better regulate the pressure that is being put on the patient's lungs and airway[2]. Automated transport ventilators have demonstrated superior safety and reliability compared to bag valve masks, and have allowed emergency responders to perform additional tasks during patient ventilation, however these devices are not optimized for prehospital emergency use[3]. These devices are utilized on many rescue helicopters and advanced ambulances, but are not found on the majority of emergency transport vehicles as they are a more expensive, cumbersome, and difficult to use option than a bag valve mask.

The VM-2000

Ventis Medical is a startup that was founded in March of 2020 with the intention of developing a small, lightweight, low-cost, and easy-to-use emergency ventilator called the VM-2000. The VM-2000 is currently in development, and will be marketed to replace bag valve masks, existing transport ventilators, and contribute to the health crisis emergency stockpile of ventilators. The VM-2000 is more affordable than other ventilators as it is built from less components and is easy to manufacture.

Its intuitive design, pre-set operating parameters, and automated self-tests allows it to be a user-friendly device that requires minimal training to operate. The VM-2000 is still sophisticated enough to provide high-level care when used by a well-trained respiratory therapist or physician.

The VM-2000 is currently designed to administer invasive ventilation, as opposed to NIV. During invasive ventilation, air enters the lungs of the patient directly through a tube placed in the trachea. The endotracheal intubation procedure required to put that tube into place is very difficult to perform, and most emergency medical services personnel are not trained to complete it. More than 33,000 adult patients die each year from mistakes during the intubation process[4]. While invasive ventilation is considered the most effective method of ventilation since it ensures the administered breaths are delivered to the lungs rather than into the stomach or leaked somewhere else, it is not always possible during an emergency situation. In this project, a non-invasive mask attachment system and ventilation feature for the VM-2000 was developed to allow the device to be used in more emergency situations when it is not possible to intubate the patient.

During the COVID-19 pandemic, the US saw massive shortages in medical equipment, especially mechanical ventilators which were vital to the treatment plan for COVID-19. It was estimated that the US would need 60,000-100,000 additional mechanical ventilators to support the same hospitalization rates observed in Europe[5]. **Figure 1**[6] depicts the disparity between available invasive and non-invasive ventilators and the demand for both types of ventilation. In the US, 1.2 million emergency medical activations require ventilation annually[2,7]. Additionally, less than 40% of patients who require out-of-hospital ventilation will survive, often due to VILI[8]. While the pandemic is more under control and demand for stockpiled ventilators has largely faded, the VM-2000 remains critical as a better alternative to current options for emergency ventilatory care. The goal of this project was to help make the VM-2000 more accessible for emergency care providers, many of whom are not trained to intubate.

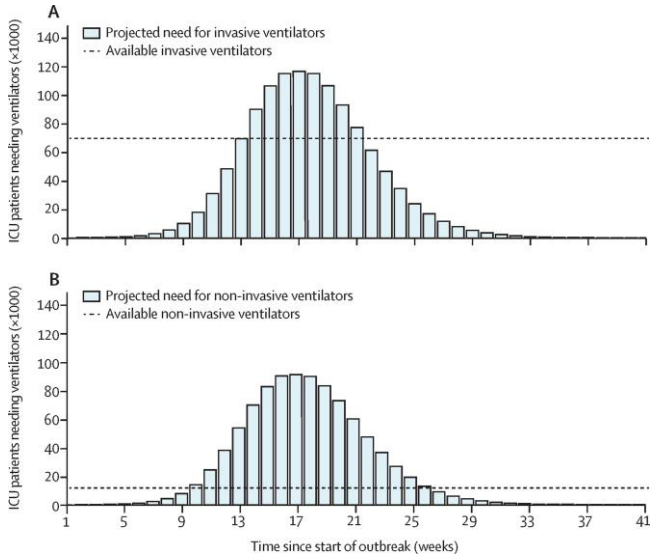

Fig. 1. Projected number of ICU patients requiring ventilators in the absence of any community interventions with R_0 = 2.5. Temporal need for (A) invasive ventilators and (B) non-invasive ventilators among ICU patients during the outbreak. The solid line indicates the routine availability of ventilators before the start of the outbreak. ICU=intensive care unit. R_0=basic reproduction number.

By iterating upon the existing ventilator design to create a non-invasive mask for the VM-2000, it can be used to ventilate patients in emergency situations when intubation is not possible. This project set out to accomplish three specific aims. First, identify a suitable mask for the mask attachment system. Second, adjust the current ventilation algorithm in the VM-2000 to accommodate NIV. Third, investigate a solution to maintain an open airway during NIV. An open airway is important because if the patient has a closed airway they may choke or air may enter the stomach which can be fatal.

Results

Mask Fit Survey

Following the collection of data from the fit survey, described below in the methods section, each mask was given a score determined by how well it fit. The total possible score for each mask was 288 points, except for Mask 2, which lacked straps for attaching to the test subject and assessing seal and tightness. **Figure 2** depicts the performance of each mask as a percentage of the total points it could have earned in the three categories of size, seal, and comfort that were assessed. Mask 4 performed the best overall. It has the highest scores in seal and comfort and was the second highest scoring mask in size versatility.

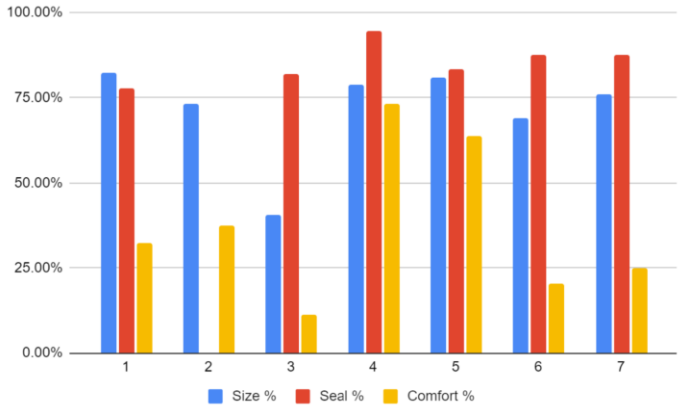

Fig. 2. Mask performance: size, seal, comfort. Results from the mask fit survey comparing the seven masks' performance across size, seal, and comfort metrics. Results are reported as percentages of the total available points the mask could have scored in each category.

CPR Model Testing

Using the data collected from the VM-2000 during each trial run with the CPR model test setup, the masks were able to be compared to each other during ventilation. **Figure 3** depicts comparisons of corrected flow measurements and volume measurements for each mask. The corrected flow value describes the amount of leak from each mask. The NIV algorithm employed by the VM-2000 approximates the leak from each breath and adjusts the next breath accordingly, recording this value as the corrected flow parameter in its run log. In **Figure 3a** the highest performing masks represent the least and the most consistent corrected flow values. Masks 1, 2, and 7 performed the best, with Mask 1 performing the best overall. Its line, the orange line, is hidden under the others.

Because the NIV mode implemented on the VM-2000 utilizes a pressure-based ventilation system, the volume waveforms of each mask were compared to ensure that the ventilator was providing sufficient tidal volumes in each breath. The VM-2000 sets the default tidal volume to

Fig. 3a. Comparison of corrected flow by mask and Fig. 3b. Comparison of volume waveforms by mask. Results comparing each masks' performance in the CPR model testing for corrected flow and volume waveforms. Each mask was tested with three 30 second trials on the CPR model patient. Run logs were extracted from the VM-2000, where flow, corrected flow, and volume measurements are recorded every 10 milliseconds during ventilation. These parameters were averaged. Corrected flow was subtracted from flow and plotted, as well as volume.

500 mL for each breath. Like the corrected flow values, Masks 1, 2, and 7 performed the best, with Mask 1 performing the best overall, as seen in **Figure 3b.** Mask 1 was determined to be the best mask for this project following CPR model testing.

Pugh Analysis

A Pugh Analysis was performed to assess the overall performance of all the masks. The results from the fit survey, the results from the CPR model testing, and additional factors such as cost and ISO compliance were all considered in this analysis. The cost of each mask ranged anywhere from $3 to $150. **Table 1** depicts the results of the Pugh analysis that was performed to provide an overall performance measurement for each mask. Masks 1 and 7 both received the most points at a value of 12. Mask 3 received the least number of points at a value of -10. Ultimately Mask 1 was chosen as the optimal mask for this application, as it was the highest performing mask in terms of corrected flow measurements.

Since Mask 1 was chosen as the most suitable mask for this project, it was used to compare the NIV mode on the VM-2000 to its standard operation of invasive ventilation. Assist-control (AC) mode is intended to be used when the patient is fully unconscious and unable to breath on their own, so the ventilator is fully responsible for all of the patient's breathing. AC mode was used to replicate endotracheal intubation in a comparison assessment of NIV mode with Mask 1. **Figure 4** depicts comparisons of flow measurements from NIV and AC operation of the VM-2000. The two waveforms express a correlation value of 0.897.

Table 1. Pugh Analysis

Criteria	Importance	Mask 1	Mask 2	Mask 3	Mask 4	Mask 5	Mask 6	Mask 7
Comfort	3	0	0	-1	1	1	-1	0
Seal	3	0	NA	0	1	0	1	1
Size Versatility	3	1	0	-1	0	1	0	0
Corrected Flow	2	1	1	0	0	-1	-1	1
ISO Compatibility	3	1	1	-1	1	1	1	1
Quick Attachment	2	0	NA	0	1	1	1	0
Weight	1	1	1	0	0	0	0	1
Size	1	1	1	1	-1	-1	-1	1
Cost	2	1	1	-1	-1	-1	-1	1
Total	20	**12**	**9**	**-10**	**8**	**6**	**0**	**12**

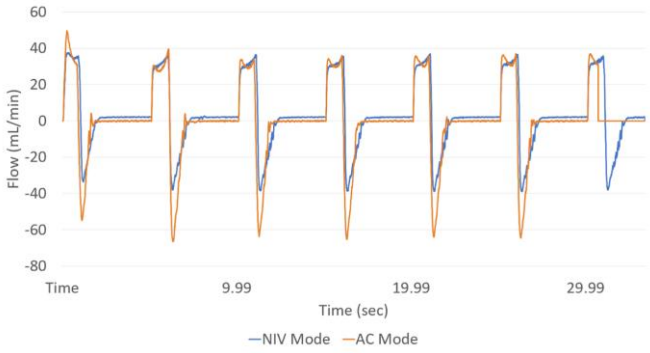

Fig. 4. Comparison of flow waveforms in NIV and AC modes. Results comparing the performance of the NIV mode to the AC mode. Three 30 second trials were performed in NIV mode using Mask 1 and the CPR model test setup. Three 30 second trials were performed in AC mode using only the test lung. Run logs were extracted from the VM-2000, where flow measurements are recorded every 10 milliseconds during ventilation. These values were averaged across the trials for each mode of ventilation and plotted against each other. The correlation between the two curves is 0.897. NIV = Non-invasive ventilation. AC = Assist-control.

3D Modeling

An initial 3D model of a neck prop that could be utilized by a caregiver during ventilation was created using computer-aided design, shown in **Figure 5**. The neck prop would promote the hands-off approach to ventilation that this design seeks to accomplish. Throughout ventilation the model would support the patient's head and neck in order to keep them at an ideal angle for the maintenance of an open airway. The modeled neck prop would allow the VM-2000 to supply effective ventilation to the lungs without the risk of air being pumped into the stomach and risking injury to the patient. This neck prop was unable to be taken into further prototyping and development due to prohibitive costs, but it was a tertiary aim that could be further improved upon in future work.

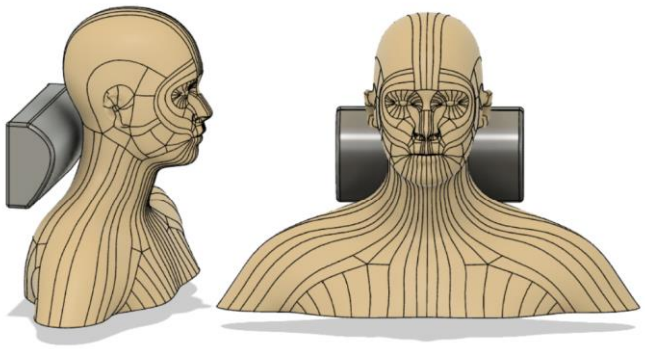

Fig. 5. 3D Model of Neck Prop. 3D model of an initial neck prop design developed using Autodesk Fusion 360, depicted alongside an open-source human face, neck, and shoulder model obtained from DiscoverThat blog.

Discussion

Conclusion

From the mask fit survey, CPR model testing, and comprehensive Pugh analysis that was performed, it was determined that the Ambu King Mask was the ideal mask for this application. Using this mask and the VM-2000, it was concluded that integration of a respiratory mask and NIV mode with the VM-2000 provided sufficient ventilation on the CPR model when compared to the invasive, AC ventilation mode with a flow waveform correlation of 0.897. The 3D model of the developed neck prop depicts a promising goal of providing operators of the VM-2000 with a mechanism for maintaining an open airway in their patients in a hands-off manner. Following the completion of this project and further development of the VM-2000 as it enters the market with an NIV feature, it will become a safer, easier, and a more effective alternative to prior methods of ventilation, especially in emergency situations for which this device is especially intended.

Challenges & Limitations

Throughout the execution of this project a few drawbacks occurred, and the developed solution is subject to some limitations. The IRB-HSR approval process needed to conduct the human mask fit study was more time consuming than expected, and resulted in testing delays that limited the data collection period. The expedited data collection process may have resulted in somewhat less meaningful results due the limited number of test subjects that could be acquired during the narrow time window. The short notice of test subject recruitment resulted in a limited age range of the individuals that participated in the study. Young adults from the ages of 19 to 24 were pooled, primarily being other university students.

Another limitation in the human mask study includes variation among researcher testing and observation. The 36 test subjects were each evaluated by one of four researchers, who each may have had their own methods of fitting the test subjects into the masks and evaluating each question as they observed the mask. This bias could have resulted in variations within the results that do not actually reflect differences in the characteristics of the masks. In the future, the goal will be to perform more controlled tests on a larger and more diverse population to account for more diverse facial structures and sizes as well as comfort preferences. Additionally, it may be helpful to test more masks in the future, especially low-cost ones which are intended for disposable use.

An aspect of the CPR model testing was similarly rushed due to delays stemming from a broken probe connection for the flow sensor in the test unit. Additionally, an order for a male-to-male tubing connector did not arrive in time for the execution of these testing procedures, forcing the creation of less than perfect modifications in order to maintain a sealed airway between the VM-2000, the testing model, and some of the masks that were tested. These two factors in combination could have resulted in errors during the corrected flow and volume measurements. Additional testing without these limitations in future work would help validate the findings reported in this study.

Additionally, the non-invasive ventilation feature that was tested during this project was built entirely by software developers at Ventis Medical. The development of the non-invasive breathing algorithm and integration of an NIV mode into the device was originally an aim of this project, but outside factors at Ventis Medical relating to their ongoing FDA approval process resulted in a more rapid development process of this feature. Instead of developing the NIV mode, the aim of this project was pivoted toward evaluating its performance and utilizing it to assess the masks alongside the human fit study that was conducted.

As mentioned in the results, another drawback of this project was that the 3D model built to address the third aim was not prototyped. Due to time constraints and prohibitively expensive 3D printing costs, the neck prop that was designed was never actually constructed, tested, or iterated upon.

An additional limitation of this project is that the solution that is being developed relies on a disposable mask option due to sterility reasons. The use of disposable masks only contributes to the widespread and worsening issue of single use plastic and medical waste within this industry, but current technological limitations prevent the standardized reusability of respiratory masks intended for emergency ventilation.

The findings of this project demonstrate great potential for the integration of non-invasive ventilation into the VM-200. Ventis Medical is currently awaiting FDA clearance for the VM-2000 to enter the market, and it will be vital to conduct more thorough testing of the NIV feature and continue iterating on the work completed through this project. Additionally, further development of the neck prop initially developed through this project will be highly beneficial in allowing ventilation to become a completely hands-off process for emergency care providers. The incorporation of additional work from a separate capstone group working to improve the VM-2000 as well offers an exciting opportunity to see further advancements in this device. Capstone Group 20 aimed to improve the accessibility and ease-of-use of the VM-2000 for emergency personnel, which will combine with the findings of this project to heighten the versatility of the ventilator.

Materials and Methods

Mask Fit Survey

To identify a suitable mask for the mask attachment system, an IRB-HSR approved mask fit study was conducted on 36 individuals. Seven respiratory masks were evaluated across a variety of criteria. Three of the masks were CPR masks and four were CPAP masks. All mask information, including cost, can be found in **Supplement 1**. All these masks vary in cost and disposability, which are important factors to consider when choosing an emergency use mask. Gender and age demographics were collected for each test subject. Then, each mask was individually fitted to the subject, and a series of questions were asked to assess the size, seal, and comfort of the mask. **Table 2** depicts an example of this survey for one test subject.

To analyze the results, size, seal, and comfort scores were calculated for each mask across all the analyzed test subjects.

- For the size score, the mask received one point for each “yes” answer to the first three questions.
- For the seal score, the mask received one point for each “yes” answer to the two seal questions.

- For the comfort score, the mask received one point for each “fine” answer and lost one point for each “too tight”, “too loose”, or “NA” answer to the sixth question.
- For the comfort score, the mask received one point for each “yes” answer and lost one point for each “no” answer to the last two questions.

Scores were calculated for each mask across all three categories and all test subjects, then reported as a percentage of the total possible score. An example of the scoring calculation is depicted in **Supplement 2**, which is based on the sample results depicted in **Table 2**. The first row of **Table 2** represents the test subject’s answers when fit with Mask 1. The scores for the first three masks are calculated using the described calculation scheme, and listed in **Supplement 2.**

Table 2. Example of Mask Fit Questionnaire

HSR 230055- Mask Fit Test			yes = 1	no = 0	tightness:	1 = too tight	0 = fine	-1 = too loose
Subject Age:	21				cushioning & comfort:	1 = yes	0 = somewhat	-1 = no
Subject Gender:	M							
	Does the mask cover the nose bridge?	Does the mask cover the mouth?	Does the mask come over the jaw?	Does the seal remain if the subject moves their face from side to side?	Does the seal remain if the subject moves their face up and down?	How tight is the mask?	Does the mask provide enough cushioning?	Does the material feel comfortable on your face?
Mask 1	1	1	1	1	1	0	1	1
Mask 2	1	1	1	NA	NA	NA	1	1
Mask 3	0	1	0	0	1	0	1	1
Mask 4	1	1	1	1	1	0	1	1
Mask 5	1	1	1	1	1	0	0	1
Mask 6	1	1	0	1	1	0	1	1
Mask 7	1	1	1	1	1	0	0	-1

CPR Model Testing

To evaluate the masks’ performance during non-invasive ventilation and assess the NIV mode integrated into the VM-2000, a CPR model test setup was developed, depicted in Figure 6. In this setup, the VM-2000 was connected to a respiratory mask which was placed onto the nose and mouth of a model patient used for CPR training. The nose and mouth airways of the model patient were connected to a piece of tubing using a piping bag and electrical tape. Then, the tubing was fed out of an opening in the model’s jaw and connected to a ventilation test lung from IMT Analytics. This setup allowed for tests to be conducted using the VM-2000 in a non-invasive manner. The NIV mode operating on the ventilator was developed at Ventis Medical, and is a CPAP-based ventilation algorithm.

During ventilation, the VM-2000 records a variety of data relating to its function and operation including pressure, flow, volume, and respiratory rate every 10 milliseconds. These values are recorded in run log files that can be downloaded off of the ventilator and analyzed using Microsoft Excel. To assess each mask's performance during NIV, the depicted test setup was built with each mask and three 30 second trials were conducted in NIV mode. The run log files from each trial were downloaded off the ventilator and the flow, corrected flow, and volume measurements were averaged for each mask using Excel. The average corrected flow values were subtracted from the average flow values for each mask and plotted against each other, then the average volume values for each mask were plotted against each other.

To assess the performance of the NIV mode, it was compared to the assist-control (AC) ventilation mode. One respiratory mask (Mask 1) was used to record three 30 second trials in NIV mode using the CPR model test setup. Then, three 30 second trials were conducted in AC mode with the VM-2000 connected directly to the test lung. The run logs from each trial were downloaded off the ventilator, and the flow measurements were averaged across the three trials for each ventilation mode using Excel. The average flow values for each ventilation mode were plotted against each other.

Pugh Analysis

A Pugh analysis was conducted to tabulate the various forms of collected data on each mask and assess their overall performance. Each assessment category is assigned an importance ranking determined by the design constraints and considerations of the mask attachment system. The evaluated criteria were comfort, seal, size versatility, corrected flow, ISO compatibility, quick attachment, weight, size, and cost. These criteria are listed alongside their importance rankings in **Table 1**. Each mask was assigned a score of 1, 0, or -1 based on its performance in each category. The scores for comfort, seal, size versatility, and quick attachment scores were determined by the results of the mask fit survey. The corrected flow scores were determined by the CPR model testing.

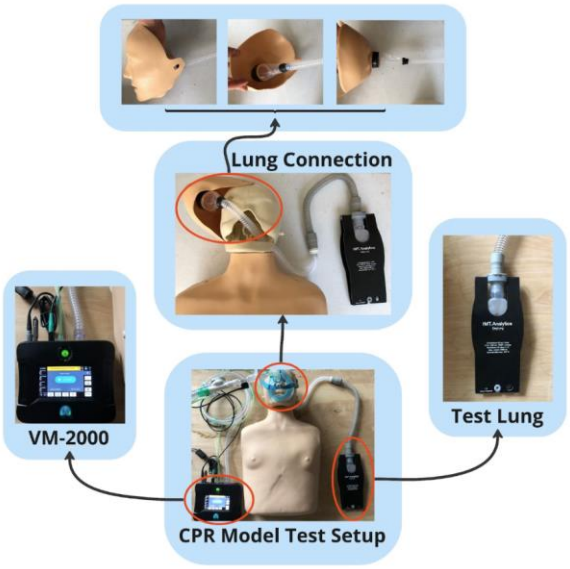

Fig. 6. CPR Model Test Setup. Flow Chart depicting the test setup used to conduct NIV trials using the VM-2000 and a model subject. The VM-2000 is connected to a tested respiratory mask, which is mounted to the CPR model. The model's airway is connected to an IMT Analytics test lung. This setup allows for the evaluation of respiratory masks and the NIV mode through the simulation of non-invasive ventilation. NIV = non-invasive ventilation.

3D Modeling

Autodesk Fusion 360 is a computer-aided design software that was used to design a solution for maintaining an open airway in the patient. A human head, neck, and shoulder model was downloaded from the DiscoverThat open-source Autodesk blog and used to help inform the design of the neck prop. The material selected for the CAD neck brace was silicone rubber. This biocompatible material would provide the patient with a comfortable and soft brace when being ventilated.

End Matter

Author Contributions and Notes

C.W.H., J.H.J, E.W.M., and E.G.M. conducted the literature review, executed the mask fit study, built the model test setup, evaluated the non-invasive ventilation mode, built the neck prop CAD model, and wrote this manuscript together in completion of this project. G.W.L. advised the authors throughout the completion of their project.

Acknowledgments

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Supplements

Supplement 1

Table S1. Mask and Pricing

Masks	Type	Cost ($)
Mask 1	Ambu King Mask with the Fisher and Paykel F&P Evora Full Strap	6
Mask 2	The lifeguard store CPR resuscitator mask #127, F&P Evora Full Strap	5
Mask 3	F&P Evora Full, small-medium	149
Mask 4	resmed air touch f20 with its own strap	129
Mask 5	F&P	135
Mask 6	Respironics Philips EE Leak 2 W/ Cap Strap	120
Mask 7	Laerdal disposable mask #4 w/ inflation port. secured with evora full strap	2.95

Supplement 2

Table S2. Example Scoring Calculations

	Size	Seal	Comfort
Mask 1	3	2	3
Mask 2	3	0	1
Mask 3	1	1	3