Plastic Drape and Copper Frame For Airway Management in the COVID-19 Era: A Case Series

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Research

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Abstract

Purpose: Airway manipulation is a high-risk procedure due to aerosolization of viral particles. This has become of paramount importance during the COVID-19 pandemic in an effort to protect personnel involved in airway management. We designed and tested a copper frame to support a plastic drape to contain aerosols and allow for reduction of risk during airway management. The “CopperHead” frame allows airway management with minimal limitations in a wide range of scenarios including elective and urgent intubations, management of unstable patients, cardiopulmonary resuscitation (CPR), bronchoscopy, and extubation. The frame was made of copper to utilize its inherent antimicrobial and antiviral properties.

Intervention and Measurements: We performed multiple simulations to measure FiO2 accumulation underneath the frame and plastic drape. We also performed defibrillations on a mannequin with the apparatus in place to evaluate for safety during times that the device is not removed prior to defibrillation, as indicated. We then deployed the device throughout our hospital and analyzed the resulting data on procedure success and infection rates in both COVID-positive and COVID-negative cohorts.

Main Results: The technique is reproducible and allows for airway manipulation in COVID-19 suspected or confirmed patients. The FiO2 under the copper frame and plastic drape increased, but quickly dispersed when the frame was removed. We performed multiple defibrillations with apparatus in place with no adverse events. We showed that with the device in place, there appears to be no hindrance to successful intubation with 94 successful procedures in 74 patients and an 87% (60/69) first-pass intubation rate, and there were no documented clinicians or respiratory therapy infections through exposures to COVID-19 positive patients.

Conclusions: The addition of a copper frame to a plastic drape over patients was an effective way to improve the safety and ease of intubation in the COVID-19 pandemic. This device was well received among our clinicians and served to benefit both intubation and extubation of recovered patients.

Key Points

We report the use of a copper intubation frame that was designed to be covered with a clear plastic sheet to facilitate airway procedures in patients infected with the novel coronavirus SARS-CoV-19. We demonstrated simulation safety studies with this technique as well as IRB-approved patient data which documented an excellent first-pass intubation rate.

Take-Home Message

We report the use of a copper intubation frame/plastic sheet device to facilitate safe airway intervention in SARS-CoV-19 patients.

Introduction
Manipulation of the airway in patients who have communicable respiratory infections is considered a high-risk procedure due to aerosolization of virus particles. Data from the SARS and COVID-19 pandemics demonstrated that intubation, airway manipulation, and even chest compressions can generate aerosolization of particles, potentially resulting in infection of health care workers.[1-9] With the current COVID-19 pandemic, many hospitals have modified their airway management protocol to minimize risk to health care workers.[10-14] As indicated by public and social media, the health care worker safety has been elevated to the forefront of COVID-19 management, with an infection rate of up to 20% in health care workers.[4, 15]

Several adjunctive therapies such as continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BIPAP) also entail high aerosolization risk, and thus have been partially replaced by alternatives such as high-flow nasal cannula for patients under investigation and those with confirmed COVID-19.[13, 14, 16] In addition to personal protective equipment (PPE), a need to minimize preoxygenation and limit bag-valve mask ventilation (BVM) during intubation and airway manipulation have led to the use of rigid acrylic boxes, pre-fabricated oxygen tents, and rapid drape-over-frame makeshift apparatuses.[10, 11, 17]

At our facility, we designed such an intubation frame to allow for rapid intubation, extubation, and safe chest compressions. We have performed simulations to replicate several patient scenarios. Simulations were based upon known or expected patient care experiences and included elective intubations, rapid response activations for decompensating patients, and unanticipated cardiac arrests requiring a code team response. We then deployed the device through the hospital with disposable drapes available for all intubations and tracked the success of the device use. A COVID-19 specific algorithm was created to guide such scenarios (Figure 1A/1B). The consensus agreement was that our preassembled CopperHead frame, used in conjunction with a ubiquitous plastic drape, allows for rapid and efficient airway and code management by both physicians and respiratory therapists. The CopperHead may be re-used for extubation to minimize cough exposure.

**Methods**

**Assembly, Use, and Cleaning of CopperHead Frame**

The CopperHead frame is assembled using copper material and its dimensions are precisely determined to allow for ease of airway management. Additional considerations of its dimensions incorporate the possible need for chest compressions, cardioversion, or defibrillation. Copper was used for its inherent antimicrobial, antifungal, and antiviral properties, smooth and easy to clean surface, and ability to withstand autoclave heat (Figure 2).[18-21] The frame is stored in a clean area where it is easily retrieved by team members. Cleaning is performed with germicidal disposal wipes containing dimethyl ethylbenzyl ammonium chlorides 0.25%, dimethyl benzyl ammonium chlorides 0.25%, and isopropyl alcohol 55.00% as the active ingredients (Super Sani-Cloth Wipes, Professional Disposables International, Inc., Orangeburg NY).
To use, the frame is placed at the patient's head and a clear plastic drape is used to cover the frame and patient. Excess drape material is tucked under the frame and or patient to create an enclosed environment. Under this plastic drape and copper frame, bag-valve-mask ventilation can be performed with minimal risk of aerosolization (Figure 3A). Arm holes are cut to allow video-assisted endotracheal intubation, nasogastric tube insertion, tracheostomy tube manipulation, bronchoscopy, or endoscopy. (Figure 3B) If staff assistance is needed, additional holes can be made on the sides.

Simulation Testing:

Oxygen Content

We placed a Laerdal Essentials© mannequin underneath the CopperHead and plastic drape. The oxygen content inside the plastic drape was measured with an All 2000 M % O2 monitor (Analytical Industries Inc., Pomona CA) calibrated in room air and with 100% fraction of inspire oxygen (FiO2) at 15 L/min. We first placed the sensor underneath the plastic drape near the sternal notch of the mannequin with a non-rebreather mask flowing at 15 L/min. FiO2 underneath the drape was measured at 1 minute, 2 minutes and 5 minutes. The test was repeated with the sensor near the right ear of the mannequin.

Defibrillation Testing

We simulated defibrillation to determine the likelihood of fire in case the CopperHead was inadvertently left in place and the patient were defibrillated. The mannequin was placed underneath the CopperHead and plastic drape with a NRB mask flowing at 15 L/min. The FiO2 was recorded before oxygen was started and again at time 0, 1, 2 and 5 minutes. The mannequin was then placed in ventricular tachycardia with defibrillator pads in place. The simulated patient was subsequently defibrillated using a Zoll R-series ALS© with the plastic drape and copper frame in place at time 0 (120 J), 1 minute (120 J), 2 minutes (150 J) and 5 minutes (200 J).

Healthy Volunteer Testing

Author DJM, an otherwise healthy 37 year old male, was placed under the CopperHead and plastic drape to account for oxygen consumption and CO2 exchange. The FiO2 underneath the drape was measured at 1, 2 and 5 minutes while the author was wearing a NRB mask flowing at 15L/min and 25L/min with an FiO2 sensor placed at the right ear.

Technique Demonstration

Demonstration of use is provided in Supplemental Digital Content as a video.

Critically Ill Patient Testing:

The CopperHead device was locally produced and widely distributed across the hospital in all wards, including the Emergency Department. Other protective devices were also made and used. Emergent, urgent and elective intubations were performed on both infected and unknown COVID status patients.
using protective methods including CopperHead frame, acrylic hood, OxyTent and plastic draping with no frame. IRB approval was obtained for patient analysis and advanced airway intervention data was evaluated for overall success of airway placement, infectious status and overall outcomes of patients.

**Results**

Mannequin FiO2 testing results are seen in Table 1. The FiO2 was notably higher when measured at the ear rather than at the sternal notch.

Mannequin defibrillation FiO2 testing results are seen in Table 2. No sparks, fire, or burns were observed. The temperature of the copper frame also did not change from ambient temperature.

For the healthy volunteer, FiO2 under the hood took approximately 2 minutes to reach 30% with a respiratory rate of 16-18 per minute. FiO2 results were comparable to the mannequin at 15L/min and increased, as expected, with the 25L/min flow rate.

In all experiments once the drape was removed the FiO2 dropped to less than 30 percent within 5 seconds.

Acutely ill patient data for 74 patients are shown in Table 4 & Table 5. The majority of intubations (69/74, 93.2%) were performed using the CopperHead device and this was compared to other barrier devices to evaluate successful placement (Table 4). 30% of patients were positive for COVID-19 (Table 5). 69 (93%) of these patients were intubated in the CopperHead device and 65 (88%) were successfully intubated on the first attempt. We note that all 74 of these patients did have successful airway placement. The GlideScope was the primary video assist device used in our hospital at a rate of approximately 90%.

Original data with HIPAA identifiers redacted is available as **Supplemental Digital Content**.

**Discussion**

We constructed a CopperHead frame to use during aerosol-generating procedures and tested it for safety in a mannequin, healthy volunteer and critically ill patients. We found that the frame was easy to use, well received by healthcare staff, and safe during defibrillation.

The risk of aerosol generation has led to significant changes in the airway algorithm for most hospitals and clinicians taking care of patients either infected with or suspected to have COVID-19. Experts recommend avoidance of airway adjuncts such as CPAP or BiPAP that could potentially increase aerosol generation. (**Figure 1A/B**) One review suggested the odds ratio (OR) of aerosolization during various procedures to be as such: a) manipulation of BiPap mask = 6.2 [95%CI 2.2, 18.1], b) endotracheal intubation = 6.6 [95%CI 2.3, 18.9], c) non-invasive ventilation = 3.1 [95%CI 1.4, 6.8], d) manual ventilation = 2.8 [95%CI 1.3, 6.4], e) collection of sputum sample 2.7 [0.9, 8.2], and f) chest compressions 1.4 [95%CI 0.2, 11.2]. The use of high flow nasal cannula is controversial and aerosol generation is perceived to be
minimal at flow rates < 30 L/min with OR 0.4 [95%CI 0.1, 1.7].[13, 14, 16, 22] Importantly, the exhaled air dispersion distance of these oxygen administration and ventilator support strategies could be as far as 100 cm.[23] Many institutions advocate for securing the ETT and closing the circuit with a viral filter in place.[10-14] In addition, the Society of Critical Care Medicine (SCCM) and the Centers for Disease Control and Prevention (CDC-P) recommend performing such aerosol-generating procedures in a negative pressure room.[14] Given the limitation in such resources, the high rate of infection in health care workers, [4] and the fear surrounding the spread of COVID-19, it is of paramount importance to pursue all strategies to contain or minimize aerosol spread. One such method is the placement of a plastic drape over the patient, which has the potential to contain the aerosols generated by any of these procedures underneath the drape and in the space around the patient's head. However, the safety of such a potentially oxygen-rich space that can pose a fire hazard, especially with defibrillation, is a concern.

Our experiments on both mannequin and human volunteer tests concluded that the FiO2 underneath the plastic drape increased within a few minutes but rapidly dissipated when the CopperHead frame and plastic drape were removed. The respiratory rate of the healthy volunteer is approximately half of what would be expected for a patient in respiratory distress. The oxygen consumption would likely increase in patient with hypoxia and tachypnea, perhaps resulting in lower measured FiO2.

Although our testing indicated that defibrillation while the CopperHead frame and plastic drape were in place was unlikely to cause a burn, shock, or fire, our recommendation is to remove the frame from the patient's bed prior to delivering any shock.

At our institution, we developed a comprehensive airway algorithm to manage all inpatient airways and code blue situations with the presumption that these patients are COVID-19 positive (Figure 1A/1B). Ranging from hemodynamically unstable to cardio- or respiratory failures/arrests, we coded and intubated patients using our device. In retrospect, we demonstrated that CPR can be performed safely and effectively while the copper frame and plastic drape are in place. If needed, the drape could be moved up to the nipple line of the patient while maintaining the ability to place defibrillator pads and access the patient's chest for effective chest compressions.

The use of the CopperHead frame, as well as other barrier devices, was found to facilitate safe endotracheal intubation as well as other procedures such as tube exchange and bronchoscopy (Table 4). Of 74 patients retrospectively analyzed, we found that 30% were indeed COVID-19 positive (Table 5). 69 (93%) of these patients were intubated in the CopperHead device and 65 (88%) were successfully intubated on the first attempt. This is comparable with data noted in the literature, both in the intensive care unit and in the operating room. [24] We note that all 74 of these patients did have successful airway placement. The GlideScope was the primary video assist device used in our hospital at a rate of approximately 90%. The C-MAC device and traditional direct laryngoscopy devices were also used in accordance with provider preference in different patient care areas. No practitioners who performed these procedures were documented or reported to have become infected with COVID-19.
The majority of patients were intubated for respiratory failure 37 (50%). Other reasons for intubation included respiratory distress 11 (15%), Airway protection including trauma or decreased mental status 17 (23%) and Cardiac Arrest 8 (11%). Of the 74 patients analyzed, 35 patients expired. 36 patients were extubated but this number included patients that were terminally extubated and also were counted as “died”. Other data such as sedation and paralytic choices were recorded. However, no correlations to these choices and outcomes have been made.

Finally, the CopperHead frame and plastic drape was used during extubation for our recovered patients as documented in Table 5. The setup and placement of the frame and drape was the same, including use of proper PPE. The hood was kept in place for two minutes post-extubation or until the patient stopped coughing and appeared calm.

The use of the CopperHead frame and plastic drape over the patient does not replace the need for enhanced PPE including bouffant or head covering, full eye protection, N95 mask or powered air purifying respirator, fluid-resistant gown, two sets of gloves, and shoe covers. It is strongly recommended to abide by droplet and contact precautions as per CDC recommendations.[10, 11, 25]

Our device is not a perfect solution for all settings and has its limitations. First, there is imperfect aerosol containment during removal of the frame. We do not have the data to determine the degree to which aerosolization is contained by the frame or is dispersed during frame removal. Furthermore, we have not determined the ideal time total to leave the plastic drape in place post extubation to minimize the release of these aerosols to the air, although we have adopted 2 minutes in our practice.

Additionally, it is possible aerosol particles may escape through the holes made in the plastic drape utilized by the hands of the intubating clinician and, when needed, the respiratory therapist. The plastic drapes used at our facility are fairly thin and do allow for minimal tearing to create a close fit to the arms and equipment passed through them while not sacrificing hand movement and dexterity. However, we recognize that this creates a leak to potential aerosols from inside the drape.

The partial opacity of the plastic drape may affect direct visualization of the airway. However, the drape can be promptly removed allowing for direct or fiberoptic laryngoscopy in case of an unsuccessful video-assisted laryngoscopy. Of note, multiple clinicians were able to successfully perform direct laryngoscopy with our device in place during simulation. It still remains, though, that the judgment of the intubating clinician must dictate the steps necessary to address any difficult airway situations which may include use of adjuncts such as a bougie or oxygenating airway exchange catheter (Cook Medical LLC, Bloomington IN) or the prompt removal of the CopperHead and plastic drape to perform additional maneuvers.

**Conclusion**

The concern for aerosol generation during airway manipulation during the COVID-19 pandemic has forced the medical community to innovate various protective barrier devices. Well established airway
management and intubation procedures have been modified as we attempt to minimize the spread of the novel coronavirus. After simulations of several devices at our institution, we demonstrate that the use of the CopperHead frame with a plastic drape is favored most by health care providers. Retrospective analysis in acutely ill patient use showed highly successful intubation rates with the protective devices in place. There were no documented provider infections documented or reported among practitioners using these barrier devices. When used correctly, the frame allows for procedures to be performed easily, with minimal obstruction, and with potentially low aerosol exposure risk to health care workers. When tested on a mannequin, this setup provides minimal fire hazard risk, even with defibrillation. We feel this device and method can be used for other safety applications and for other known aerosolized diseases. More research, which is currently being undertaken at our and other institutions, is needed to understand the full aerosol pattern within a room during aerosol-generating procedures to refine the use of this device.

**Declarations**

**Funding:** N/A

**Conflicts of Interest:** None

**Ethics Approval:** Approved 5/13/2020 by Loma Linda University Medical Center IRB #5200158, judged to be minimal risk, with informed consent and HIPAA authorization waived

**Availability of Data and Material:** Included as a supplemental data file

**Code Availability:** N/A

**Author Roles**

DJM: Development of device, user testing of device, performed simulation testing, wrote and edited manuscript

BH: Development of device, user testing of device, performed simulation testing, edited manuscript

AAC: User testing for device, assisted with protocol development, edited manuscript

PG: User testing for device, assisted with protocol development, edited manuscript

MC: User testing for device, assisted with protocol development, edited manuscript

DT: User testing for device, assisted with protocol development, edited manuscript

DS: Assisted with training users on the device, edited manuscript

SM: Assisted with protocol development, edited manuscript
LKS: User testing for device, assisted with protocol development, assisted with training users on the device, edited manuscript

DDS: Performed simulation testing, assisted with training users on the device, edited manuscript

IRD: Assisted with protocol development, facilitated device manufacturing, edited manuscript

HBN: User testing for device, assisted with protocol development, edited manuscript

KM: Development of device, user testing of device, performed protocol development, facilitated patent process, edited manuscript

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Tables

**Table 1: FiO2 on Mannequin**

| Time Interval: Minutes in subscript | Sensor Location: Sternum | Sensor Location: Right Ear |
|-----------------------------------|--------------------------|----------------------------|
| $T_0$                             | 21.2%                    | 21.2%                      |
| $T_1$                             | 22.6%                    | 40.1%                      |
| $T_2$                             | 27.0%                    | 43.4%                      |
| $T_5$                             | 34.5%                    | 45.5%                      |

Oxygen flow Rate: 15 L/min via NRB mask

**Table 2: FiO2 on Mannequin during Defibrillation**

| Time Interval: Minutes | Sensor Location: Right Ear | Defibrillation Energy |
|------------------------|----------------------------|-----------------------|
| $T_0$                  | 20.2%                      | 120J                  |
| $T_1$                  | 48.5%                      | 120J                  |
| $T_2$                  | 51.1%                      | 150J                  |
| $T_5$                  | 62.4%                      | 200J                  |

Oxygen flow Rate: 15 L/min via NRB mask

**Table 3: FiO2 on Healthy Volunteer**
Table 4: Protective Device Selection for Invasive Procedures

| CopperHead | Other Devices* |
|------------|----------------|
| **Intubation** | 69 | 5 |
| First Pass | 60 (87%) | 5 (100%) |
| Second Attempt | 5 (7%) | 0 |
| Third Attempt | 3 (4%) | 0 |
| Not Documented | 1 (1%) | 0 |
| **Tube Exchange** | 5 | 0 |
| **Bronchoscopy** | 3 | 0 |
| **Reintubations** | 4 | 0 |
| **Code** | 13 | 1 |

* Includes OxyTent, Acrylic Box & Drape Only

Table 5: Invasive Procedures Compared with COVID Negative & Positive
|                          | Total Patients | %   | COVID + | %    | COVID - | %    | Not Tested | %    |
|--------------------------|----------------|------|---------|------|---------|------|------------|------|
|                          | 74             | 22   | 29.7%   | 50   | 67.6%   | 2    | 2.7%       |
| **Protection Device**    |                |      |         |      |         |      |            |
| CopperHead               | 69             | 19   | 25.7%   | 48   | 64.9%   | 2    | 2.7%       |
| Other Devices*           | 5              | 3    | 4.1%    | 2    | 2.7%    | 0    | 0.0%       |
| **Intubation Device**    |                |      |         |      |         |      |            |
| Glide Scope              | 67             | 20   | 27.0%   | 46   | 62.2%   | 1    | 1.4%       |
| CMAC (Video Assist)      | 4              | 0    | 0.0%    | 4    | 5.4%    | 0    | 0.0%       |
| Direct                   | 3              | 2    | 2.7%    | 0    | 0.0%    | 1    | 1.4%       |
| **Intubation Reason**    |                |      |         |      |         |      |            |
| Respiratory Failure      | 37             | 18   | 24.3%   | 19   | 25.7%   | 0    | 0.0%       |
| Respiratory Distress     | 11             | 2    | 2.7%    | 8    | 10.8%   | 1    | 1.4%       |
| Airway Protection        | 17             | 2    | 2.7%    | 15   | 20.3%   | 0    | 0.0%       |
| Cardiac Arrest           | 8              | 0    | 0.0%    | 7    | 9.5%    | 1    | 1.4%       |
| Other (GI Procedure)     | 1              | 0    | 0.0%    | 1    | 1.4%    | 0    | 0.0%       |
| **Intubation Attempts**  |                |      |         |      |         |      |            |
| First Pass (1)           | 65             | 18   | 24.3%   | 45   | 60.8%   | 2    | 2.7%       |
| Second Attempt (2)       | 5              | 2    | 2.7%    | 3    | 4.1%    | 0    | 0.0%       |
| Third Attempt (3)        | 3              | 1    | 1.4%    | 2    | 2.7%    | 0    | 0.0%       |
| Not Recorded             | 1              | 1    | 1.4%    | 0    | 0.0%    | 0    | 0.0%       |
| **Sedation**             |                |      |         |      |         |      |            |
| Etomidate                | 56             | 20   | 27.0%   | 35   | 47.3%   | 1    | 1.4%       |
| Ketamine                 | 8              | 0    | 0.0%    | 8    | 10.8%   | 0    | 0.0%       |
| Propofol                 | 1              | 0    | 0.0%    | 0    | 0.0%    | 1    | 1.4%       |
| None                     | 6              | 1    | 1.4%    | 5    | 6.8%    | 0    | 0.0%       |
|                      |         |         |         |         |         |         |         |         |
|----------------------|---------|---------|---------|---------|---------|---------|---------|---------|
| Not Recorded         | 3       | 4.1%    | 1       | 1.4%    | 2       | 2.7%    | 0       | 0.0%    |
| **Paralytic**        |         |         |         |         |         |         |         |         |
| Rocuronium           | 50      | 67.6%   | 18      | 24.3%   | 30      | 40.5%   | 2       | 2.7%    |
| Succinylcholine       | 14      | 18.9%   | 2       | 2.7%    | 12      | 16.2%   | 0       | 0.0%    |
| None                 | 7       | 9.5%    | 1       | 1.4%    | 6       | 8.1%    | 0       | 0.0%    |
| Not Recorded         | 3       | 4.1%    | 1       | 1.4%    | 2       | 2.7%    | 0       | 0.0%    |
| **Outcome**          |         |         |         |         |         |         |         |         |
| Extubated            | 36**    | 48.6%   | 8       | 10.8%   | 26      | 35.1%   | 0       | 0.0%    |
| Died                 | 35      | 47.3%   | 7       | 9.5%    | 27      | 36.5%   | 1       | 1.4%    |

* Includes OxyTent, Acrylic Box & Drape Only

** Includes terminal extubation