

Negative pressure patient isolation device to enable non-invasive respiratory support for COVID-19 and beyond

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BACKGROUND

As healthcare systems adapt to living with the SARS-CoV-2 virus, the risk of aerosolising infectious viral particles has emerged as an ongoing threat in hospitals when treating patients suspected or confirmed to have COVID-19; especially as we head into a second wave this winter.

SARS-CoV-2 is primarily a droplet contagion, spreading through close contact with respiratory droplets of an infected person.¹ Droplet particles range from 5 to 100 µm and remain suspended in the air for just seconds in the wake of an infected individual.² In contrast, aerosol particles are <5 µm, can travel over 10 m and can remain suspended for hours in the wake of an infected person. As we learn more about SARS-CoV-2 there is mounting concern that aerosols are a significant driver of transmission.^{3–6}

There are certain respiratory interventions performed that generate aerosols from the patient and thus have become a cause for concern as SARS-CoV-2 continues to spread. The aforementioned non-invasive aerosolising procedures (NAPs) include, but are not limited to, high flow nasal cannula, medication nebulisers, continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP).⁷ These are all important intermediate options for respiratory support for patients prior to needing invasive intubation.

Due to the risk of aerosolising virus particles, many hospital administrations and published guidelines have strongly recommended against the use of NAPs.⁸ Such policies have the consequence of

Summary box

What are the new findings?

- ▶ Nosocomial spread of COVID-19 and other airborne infectious diseases can occur during non-invasive aerosolising procedures.
- ▶ The in-room suction system in most hospitals can generate enough pressure to create a negative pressure environment around a patient's head.
- ▶ The ARIEL is an effective and low-cost solution to allow safe, widespread use of non-invasive positive pressure respiratory support devices.

How might it impact on healthcare in the future?

- ▶ Effective, low cost and packable solutions are required to enable deployment at scale.
- ▶ Nosocomial spread of COVID-19 and other airborne infectious diseases will continue to be a threat and infrastructure such as The ARIEL can help mitigate this risk.

forcing patients with COVID-19 directly to intubation. Thus, there is a need to enable the use of these important intermediate airway support interventions to avoid preventable intubations.

There are no existing on-market technologies available in the USA that reduce the risk of aerosolisation enough to enable the use of non-invasive ventilation (NIV), despite calls for them in high-profile medical publications.^{9–11}

Recently, there has been a groundswell of publications on innovations that are intended to protect healthcare professionals (HCPs) during aerosol-generating

airway procedures, such as intubation boxes¹² and patient isolation chambers.^{13–15}

While these innovations address the same need we discuss above, we recognise several limitations in these products. The bed-mounted designs in particular create a large contaminated area which requires the use of a powerful external vacuum pump to create the negative pressure environment, limiting their usability in health systems. Additionally, the bed-mounted designs do not account for variability in patient positioning such as sitting up, which is a desired positioning for patients in respiratory distress. While it is ideal from an efficacy standpoint to minimise the contaminated chamber volume that must be evacuated, too small of a chamber can impede compatibility with all existing NIV modalities. This is seen in the negative pressure helmet,¹⁵ which cannot accommodate a CPAP or BiPAP mask.

The Aerosol Elimination Device (ARIEL) we present here is a solution that meets these identified needs. It is a patient-level negative pressure isolation system designed to evacuate aerosols generated by NAPs which leverages existing healthcare infrastructure. The system comprises a cap, shroud, viral filter and tubing. When assembled, the device provides room for standard NAP masks and tubing and creates a laminar flow chamber allowing ambient air to enter the chamber at the loose drape at the bottom of the device and be evacuated through the viral filter and the exhaust port on the top. The vacuum source for the device is the in-room wall suction standard in most hospital rooms which is already used to handle biohazardous material. However, to prevent viral particles from entering the hospital heating, ventilation, and air conditioning (HVAC) system, a viral filter is placed in line with the exhaust port and all suctioned air is passed through the filter. The full device deployed on a human model in an emergency department room can be seen in [figure 1](#).

METHODS

The ARIEL was developed with the goal of designing a lightweight, disposable solution that could securely attach to the patient, while allowing freedom of head movement when sitting or lying down. The design underwent six rounds of prototyping, each generation refined based on user feedback and efficacy testing. Once at the final design, the efficacy of this device was determined using three test methods: flow generation, aerosol clearance and flow visualisation.

Flow generation within the ARIEL was determined using a Fluke 922 flow-meter. The sensing probe of the flow-meter was introduced in the evacuation tube distal to the filter in line with the in-room suction. The flow within the ARIEL was measured by placing the sensing probe through a small slit created in the shroud in front of the face shield.

Aerosol clearance of the ARIEL was quantitatively measured using a medication nebuliser, the therapy that generates the most aerosol particles. The nebuliser

generates significantly more particles per second than a coughing event.¹⁶ An off-the-shelf medication nebuliser was used, and water was nebulised through a standard non-rebreather mask on a manikin. Aerosolised particles were measured over the course of 3 min with and without the ARIEL in place using a HandiLaz handheld laser particle counter detecting 0.3, 0.5 and 5 μm particles ([figure 2](#)). For this testing only the 0.3 and 0.5 μm particles were considered, as those are the applicable size buckets to measure aerosols.

Flow patterns for the ARIEL were visualised using a smoke generator. The smoke was administered through standard anaesthesia circuit corrugated tubing connected to a standard face mask worn by the manikin. The smoke flow patterns and leaks were visually observed with and without the ARIEL device turned on. The aerosol clearance was also measured during this test using the same HandiLaz laser particle counter.

RESULTS

The flow generated by a standard patient room suction regulator was between 120 and 140 L/min. Despite the variation in regulators which limits the pressure generated by the system, and variation in brands of viral filters used, the system was able to reach a flow of at least 120 L/min. The velocity of the flow within the ARIEL was measured between 0.90 and 1.35 m/s.

During aerosol clearance testing the ARIEL cleared 96.5% of aerosol particles overall including 94.2% of 0.3 μm particles, and 98.9% of 0.5 μm particles compared with control.

For flow visualisation, the smoke input flow was measured at 120 L/min. With the ARIEL turned on there was no leakage of smoke escaping the chamber compared with when no suction applied. The particle clearance during this test with the ARIEL was measured at 99% clearance of particles 5 μm and smaller.

DISCUSSION

The results of this testing suggest that the ARIEL could be safely used as a patient-level isolation device. The bar for efficacy for this device was set to be equivalent to an N95 mask, namely the ability to eliminate 95% of aerosols (particles <5 μm) generated. This specification was chosen as an N95 is the standard personal protective equipment (PPE) used when interacting with patients with COVID-19. The results of the testing described above show that the ARIEL meets and exceeds this specification. HCPs would still be encouraged to wear standard PPE (N95 mask, face shield, gown and gloves) for treating confirmed or suspected patients with COVID-19.

To ensure the safety of the ARIEL the test methods were designed for the most extreme circumstances. The test methods used above do not account for any

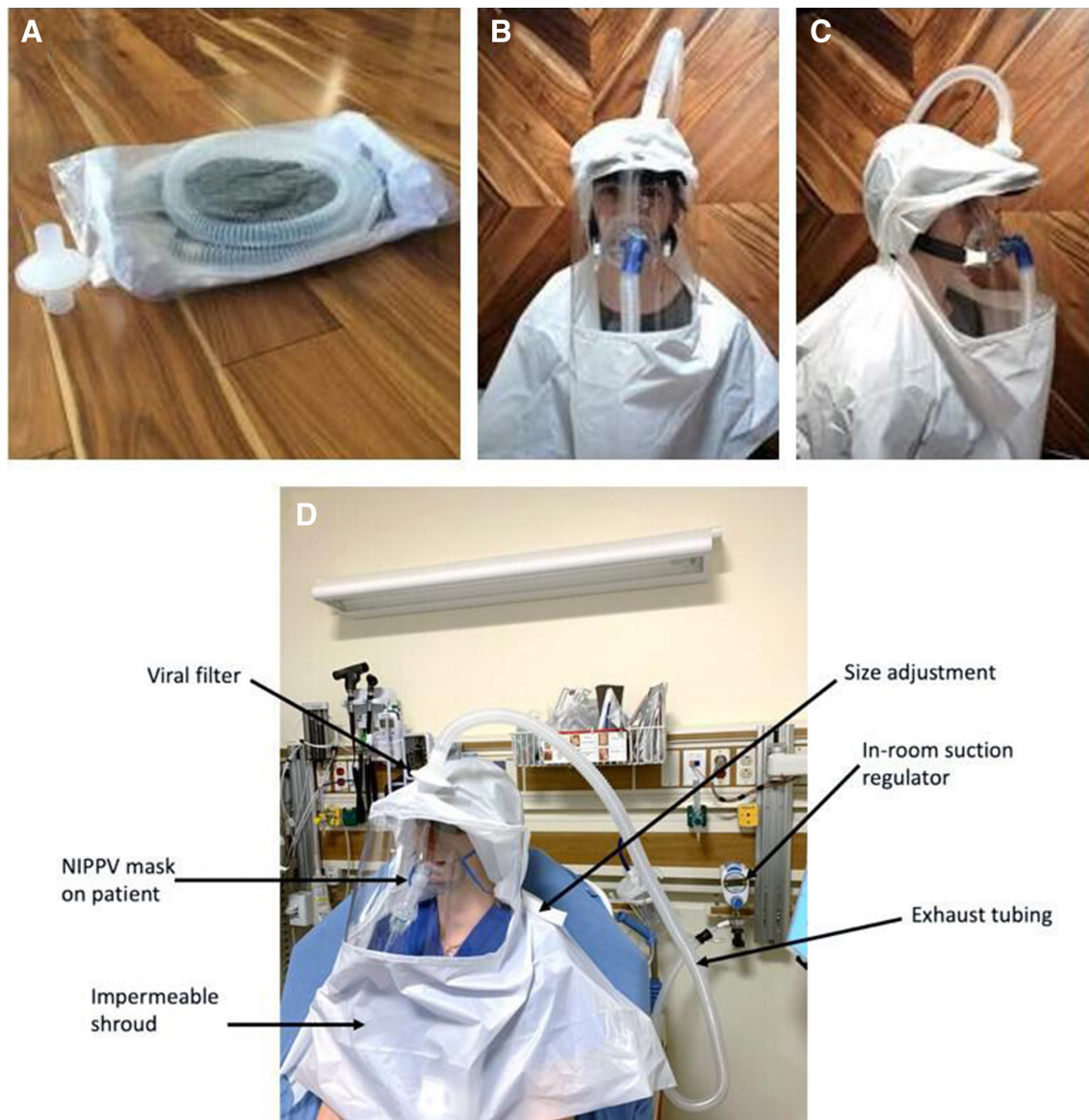


Figure 1 (A) The ARIEL prototype flat packed, viral filter for scale, (B–C) front and side views, (D) fully deployed on a human model in a patient room. ARIEL, Aerosol Elimination Device; NIPPV, non-invasive positive-pressure ventilation.

containment through patient inhalation or an expiratory limb, suggesting sufficient safety margin related to user or patient variation. Similarly, the result from the aerosol clearance test shows a significant decrease in escaped aerosols even without accounting for any inhaled portion of the administered medication. One concern that could arise when using the ARIEL with NAPs is the aerosol generation related to the velocity of the inflow limbs of the therapies. The maximum flow rate of the inflow limbs for both CPAP and BiPAP is 60 L/min which is well below the flow capacity of the ARIEL at 120 L/min.

While the ARIEL meets many of the identified clinical needs, there are several limitations to its design. It is intentionally designed to not be a restraint; therefore, it is susceptible to an uncooperative patient removing the device. It cannot be used for intubating patients as it does not allow sufficient access to the patient's

airway while maintaining its flow. The rigid headpiece prevents collapse of the shroud around the patient's head, and the patient by definition will be receiving supplemental oxygen making the risk of asphyxiation extremely low; however, there is no alarm system in place if the patient's airflow were to suddenly be interrupted. Significant clinical need exists around patient isolation during transport, and the ARIEL would not suffice without the addition of a portable suction source. Finally, the ARIEL relies on the in-room suction commonly found in well-resourced hospitals, but that infrastructure is sparse to non-existent in resource-constrained settings.

CONCLUSION

It has become apparent that SARS-CoV-2 will be an ongoing risk in our communities and healthcare system and the inability to use NAPs is preventing

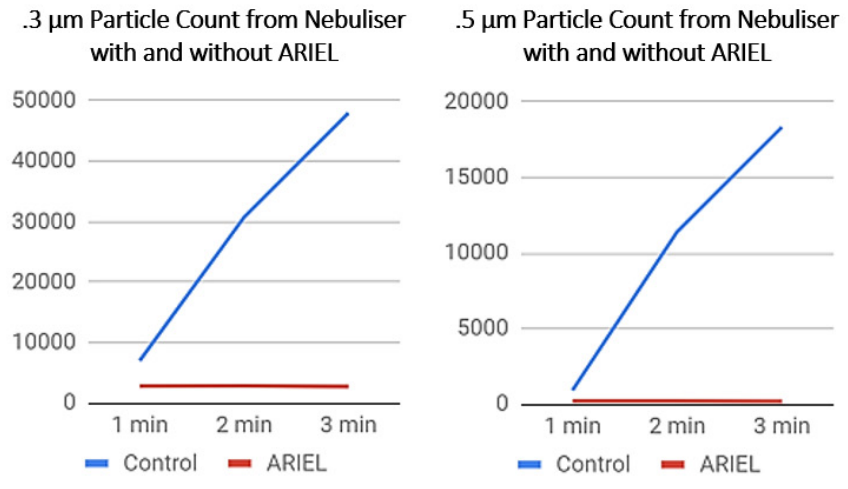


Figure 2 (Left) Particle count test set-up. (Right) Counts of 0.3 and 0.5 µm particles during 3 min of nebulising without the ARIEL (control) and with the ARIEL. ARIEL, Aerosol Elimination Device

the optimal care of patients. The ARIEL device proposed above meets stringent safety specifications and has the potential to enable the use of NAPs for this population in a way that it is safe for healthcare professionals.

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