



ELMO 1.0: a helmet interface for CPAP and high-flow oxygen delivery

Marcelo Alcantara Holanda^{1,2}, Betina Santos Tomaz³,
David Guabiraba Abitbol de Menezes⁴, Juliana Arcanjo Lino⁴,
Gabriela Carvalho Gomes⁴

TO THE EDITOR:

A few months after the description of the first case of COVID-19 in China, the disease became a pandemic. More than 50 million people have been infected with SARS-CoV-2, and more than 1 million deaths have been confirmed worldwide.⁽¹⁾ The number of COVID-19 cases in Brazil has been high, Brazil ranking third among the countries with the highest death toll⁽²⁾; with no immediate resolution in sight, there is a possibility of a second wave of infection, which several countries are currently facing.⁽³⁾

Infection with SARS-CoV-2 causes COVID-19, the clinical spectrum of which ranges from no symptoms to flu-like symptoms such as fever, fatigue, dry cough, and dyspnea.⁽⁴⁾ Although most cases progress favorably, 15-20% of patients develop severe forms of COVID-19 (including ARDS), requiring ventilatory support. In a case series of hospitalized patients with COVID-19 in the USA, 14% required admission to the ICU, and those who required mechanical ventilation had high mortality rates (88.1%).⁽⁵⁾

The management of COVID-19-related respiratory failure is quite challenging. First, although noninvasive ventilation can prevent endotracheal intubation and its complications, the high flow rates increase the risk of aerosolization and the spread of the virus, therefore increasing the rate of infection in health professionals.⁽⁶⁾ Second, the number of ICU beds available in the beginning of the pandemic was lower than the total number of infected patients requiring noninvasive ventilation.⁽⁷⁾ Third, ventilator manufacturers worldwide were unable to meet the surge in demand. The spectrum of COVID-19 presentation includes moderate to severe ARDS, which has the highest rates of morbidity and mortality and is the most challenging with regard to managing ventilatory support.

In this context, a helmet interface—a transparent hood that covers the entire head of the patient, with a soft collar neck seal—allows safe and comfortable delivery of positive airway pressure to patients with moderate to severe acute respiratory failure, potentially reducing intubation rates.^(7,8) Under the coordination of the *Escola de Saúde Pública do Ceará Paulo Marcelo Martins Rodrigues*, located in the city of Fortaleza, Brazil, a public-private partnership was established among research funding agencies, universities, and sectors of the industry in the state of Ceará, forming a multidisciplinary task force to develop the first helmet interface manufactured in Brazil. The device was developed in record time (three months)

and was designated ELMO 1.0 (*e/mo* being a Portuguese word for helmet), being patented in Brazil (BR 20 2020 014212 2; ANVISA no. 82072609001).

The ELMO 1.0 was based on similar devices in the literature^(9,10) and consists of a transparent nontoxic autoclavable PVC hood (height, 270 mm; diameter, 290 mm) and a silicone rubber collar neck seal attached to a polypropylene ring. The hood has a posterosuperior inhalation port (inlet) and a contralateral anteroinferior exhalation port (outlet). The silicone rubber collar neck seal can be adjusted to fit different neck circumferences. The ELMO 1.0 is a noninvasive ventilation device that prevents air leaks and droplet dispersion, as well as delivering CPAP as high as 10-15 cmH₂O, being particularly interesting for use in COVID-19 patients requiring oxygen therapy (Figure 1).

Nine prototypes were developed. For quality and patient risk assessment, usability tests were performed with six health professionals (two physicians, two physiotherapists, and two nurses) with experience in mechanical ventilation and four healthy volunteers (one woman and three men; mean age, 38.5 years; range, 24.0-51.5 years).

All usability tests were performed in a technological innovation laboratory designed specifically for the present study. In the laboratory, the health professionals watched an instructional video on how to assemble the system and performed tasks aimed at identifying potential problems when using the ELMO 1.0. They were asked to do the following: 1) check the patient neck circumference; 2) recognize, assemble, and check the ELMO 1.0; 3) place the ELMO 1.0 interface on the patient; 4) initiate delivery of CPAP and oxygen therapy; 5) check the pressure inside the ELMO 1.0 interface by using an analog cuff manometer and a CPAP setting of 10 cmH₂O; 6) give water to a patient receiving helmet noninvasive ventilation with the ELMO 1.0; 7) change the position of the patient; and 8) remove the ELMO 1.0 interface. The problems identified by the health professionals were classified as follows: a) minor problems—problems requiring no immediate changes; b) intermediate problems—problems requiring changes, albeit not immediately; and c) major problems—problems requiring immediate changes.

A total of 22 problems were reported, with suggestions regarding connections for inhaled and exhaled gas flow, access to the patient, and instructions in the manual, as well as other suggestions that were incorporated into the final prototype, which is presented here. The time

1. Escola de Saúde Pública do Ceará Paulo Marcelo Martins Rodrigues, Fortaleza (CE) Brasil.

2. Disciplinas de Terapia Intensiva e Pneumologia, Departamento de Medicina Clínica, Universidade Federal do Ceará, Fortaleza (CE) Brasil.

3. Programa de Pós-Graduação em Ciências Médicas, Universidade Federal do Ceará, Fortaleza (CE) Brasil.

4. Fundação Cearense de Apoio ao Desenvolvimento Científico e Tecnológico, Fortaleza (CE) Brasil.

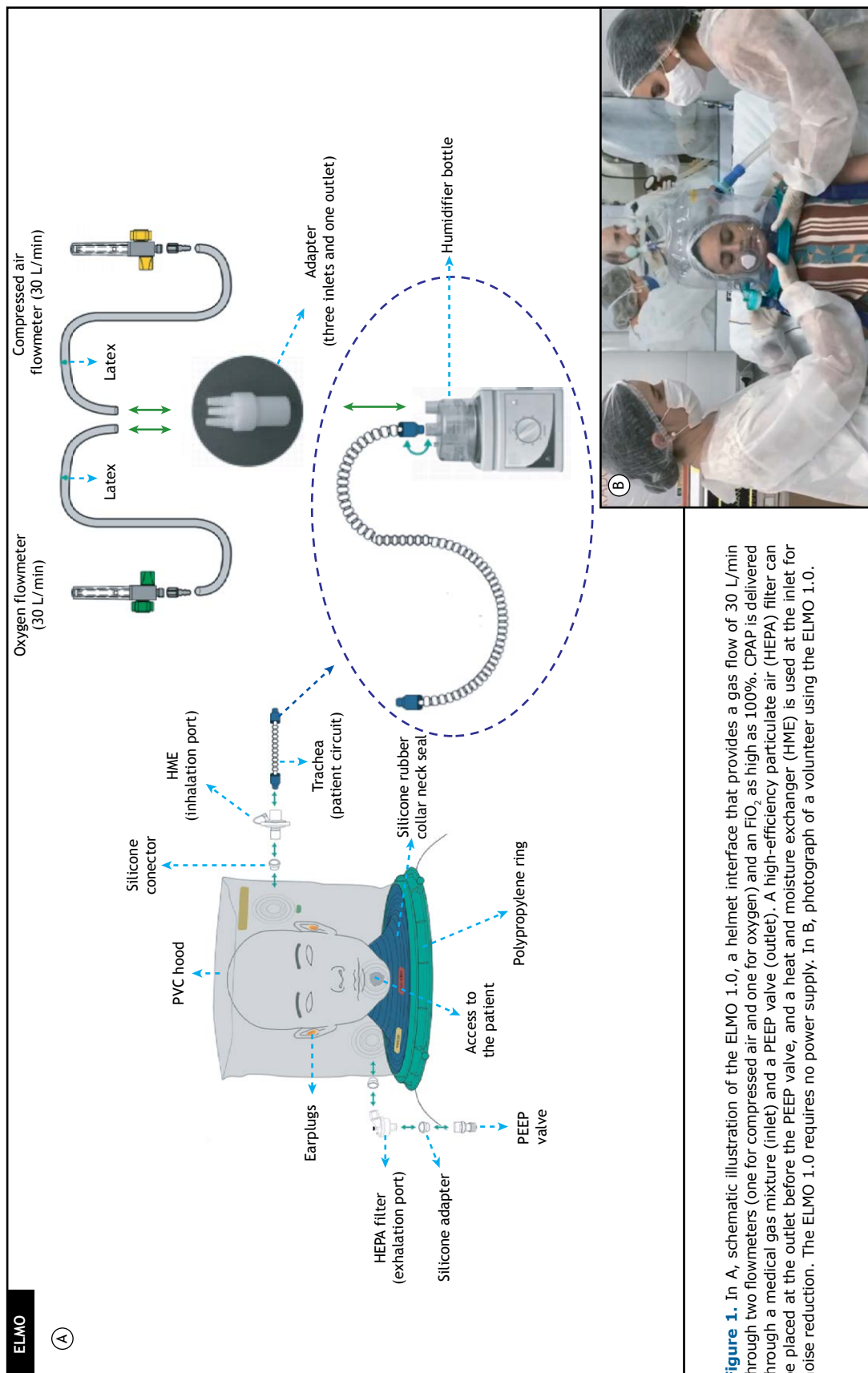


Figure 1. In A, schematic illustration of the ELMO 1.0, a helmet interface that provides a gas flow of 30 L/min through two flowmeters (one for compressed air and one for oxygen) and an FiO_2 as high as 100%. CPAP is delivered through a medical gas mixture (inlet) and a PEEP valve (outlet). A high-efficiency particulate air (HEPA) filter can be placed at the outlet before the PEEP valve, and a heat and moisture exchanger (HME) is used at the inlet for noise reduction. The ELMO 1.0 requires no power supply. In B, photograph of a volunteer using the ELMO 1.0.

to perform each task was measured, assembling and checking the ELMO 1.0 being the task that took the longest to complete (7.0 ± 2.0 min).

After the usability tests were completed, a visual analog scale was used in order to assess interface comfort, ranging from zero (uncomfortable) to 10 (comfortable). The median score was 8.5 (range, 7.0-9.0). Volunteers used the ELMO 1.0 for a mean time of 47.5 min (range, 41.2-57.5 min), during which minimal adverse effects were observed, including hyperemia in the posterior cervical region (in 1 participant), without the need for discontinuation or additional measures.

After approval of the final prototype, we tested the ELMO 1.0 noise level and pressure (CPAP), the former ranging from 45 dB to 65 dB and the latter ranging from 12 cmH₂O to 13 cmH₂O. Carbon dioxide rebreathing was assessed by sidestream capnography with a standard nasal cannula and a gas mixture at different flow rates (30 L/min, 40 L/min, 50 L/min, and 60 L/min) for inspired carbon dioxide tension (PiCO₂) measurement. Flow rates greater than 40 L/min resulted in a PiCO₂ of 0-1 mmHg, whereas a flow rate of 30 L/min resulted in a PiCO₂ of 2-5 mmHg. A higher flow rate translated to a lower likelihood of carbon dioxide rebreathing, a finding that is consistent with the literature.⁽¹⁰⁾

In a short period of time, we have developed a new helmet interface for comfortable CPAP delivery through a gas mixture (oxygen and compressed air), with minimal adverse effects, effective positive airway pressure, an effective seal, and a reduced risk of carbon dioxide rebreathing. The ELMO 1.0 is a device that can be used in clinical tests to provide ventilatory support for patients with acute hypoxemic respiratory failure secondary to COVID-19 or other causes.

ACKNOWLEDGMENTS

We would like to thank the *Escola de Saúde Pública do Ceará* (ESP, Ceará State School of Public Health), *Esmaltec S/A*, the *Federação das Indústrias do Estado do Ceará* (FIEC, Federation of Industries in the State of Ceará), the *Fundação Cearense de Apoio ao Desenvolvimento Científico e Tecnológico* (FUNCAP, Foundation for the Support of Scientific and Technological Development in the State of Ceará), the *Serviço Nacional de Aprendizagem Industrial* (SENAI, Brazilian National Service for Industrial Training), the *Secretaria de Saúde do Estado do Ceará* (SESA, Ceará State Department of Health), the *Universidade Federal do Ceará* (UFC, Federal University of Ceará), and the *Universidade de Fortaleza* (UNIFOR, University of Fortaleza) for their support in the development of the ELMO 1.0.

FINANCIAL SUPPORT

This study received financial support from the *Escola de Saúde Pública do Ceará* (ESP, Ceará State School of Public Health) and the *Fundação Cearense de Apoio ao Desenvolvimento Científico e Tecnológico* (FUNCAP, Foundation for the Support of Scientific and Technological Development in the State of Ceará).

AUTHOR CONTRIBUTIONS

MAH, GCG, JAL, BST, and DGAM: conception and planning of the study; data collection and tabulation; statistical analysis and creation of tables and figures; drafting and revision of the manuscript; formatting of the manuscript in accordance with the JBP instructions for authors; and approval of the final version.

REFERENCES

1. Johns Hopkins University [homepage on the Internet]. Baltimore (MD): the University; c2020 [cited 2020 Nov 10]. COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE). Available from: <https://coronavirus.jhu.edu/map.html>
2. Holanda MA, Pinheiro BV. COVID-19 pandemic and mechanical ventilation: facing the present, designing the future. *J Bras Pneumol*. 2020;46(4):e20200282. <https://doi.org/10.36416/1806-3756/e20200282>
3. Ali I. COVID-19: Are We Ready for the Second Wave?. *Disaster Med Public Health Prep*. 2020;14(5):e16-e18. <https://doi.org/10.1017/dmp.2020.149>
4. Centers for Disease Control and Prevention (CDC) [homepage on the Internet]. Atlanta: CDC; c2020 [cited 2020 Nov 10]. COVID-19: Guidance Documents. Available from: <https://www.cdc.gov/coronavirus/2019-ncov/communication/guidance-list.html?Sort=Date%3A%3Adesc>
5. Richardson S, Hirsch JS, Narasimhan M, Crawford JM, McGinn T, Davidson KW, et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area [published correction appears in *JAMA*. 2020 May 26;323(20):2098]. *JAMA*. 2020;323(20):2052-2059. <https://doi.org/10.1001/jama.2020.6775>
6. Cabrini L, Landoni G, Zangrillo A. Minimise nosocomial spread of 2019-nCoV when treating acute respiratory failure. *Lancet*. 2020;395(10225):685. [https://doi.org/10.1001/S0140-6736\(20\)30359-7](https://doi.org/10.1001/S0140-6736(20)30359-7)
7. Patel BK, Wolfe KS, Pohlman AS, Hall JB, Kress JP. Effect of Noninvasive Ventilation Delivered by Helmet vs Face Mask on the Rate of Endotracheal Intubation in Patients With Acute Respiratory Distress Syndrome: A Randomized Clinical Trial. *JAMA*. 2016;315(22):2435-2441. <https://doi.org/10.1001/jama.2016.6338>
8. Armirfarzan H, Shanahan JL, Schuman R, Leissner KB. Helmet CPAP: how an unfamiliar respiratory tool is moving into treatment options during COVID-19 in the US. *Ther Adv Respir Dis*. 2020;14:1753466620951032. <https://doi.org/10.1177/1753466620951032>
9. Lucchini A, Giani M, Isgrò S, Rona R, Foti G. The "helmet bundle" in COVID-19 patients undergoing non invasive ventilation. *Intensive Crit Care Nurs*. 2020;58:102859. <https://doi.org/10.1016/j.iccn.2020.102859>
10. Radovanovic D, Rizzi M, Pini S, Saad M, Chiumello DA, Santus P. Helmet CPAP to Treat Acute Hypoxemic Respiratory Failure in Patients with COVID-19: A Management Strategy Proposal. *J Clin Med*. 2020;9(4):1191. <https://doi.org/10.3390/jcm9041191>