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A novel barrier device and method for protection against airborne pathogens during endotracheal intubation

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Editor,

Healthcare professionals involved in aerosol-generating procedures, such as endotracheal intubation are at high risk of exposure to respiratory pathogens, such as SARS-CoV-2,[1,2] despite current preventive measures including personal protective equipment.[3] Past attempts to mitigate the risk of exposure to aerosols and droplets during endotracheal intubation include barrier devices, such as aerosol boxes; however, these have been withdrawn from clinical use because of concerns about prolonged intubation times and risk of hypoxemia.[4–6]

We developed a novel barrier mouthpiece, the Airway Shield, to protect clinicians from exposure to airborne particles generated during endotracheal intubation, while facilitating the procedure itself. The Airway Shield is made of a soft thermoplastic elastomer (TPE) medical grade plastic and consists of a shield, which covers the patient's mouth; a pre-cut seal in the centre of the shield that permits the introduction of the laryngoscope and endotracheal tube whilst providing a barrier against airborne particles; and a guiding channel that facilitates intubation by creating a semirigid pathway, which helps in directing the endotracheal tube towards the larynx (Fig. 1). Endotracheal intubation with the Airway Shield is performed in three steps. First, during induction, the device is placed: the guiding channel is introduced into the mouth of the patient following the palate, until the shield covers the mouth. Second, standard endotracheal intubation is performed, with the laryngoscope and endotracheal tube introduced through the seal. Finally, once the endotracheal tube is in place, the ETT cuff is inflated and the ventilator is connected, the device is torn open and removed. A video explaining how the Airway Shield™ works is presented with the supplementary material (Appendices A, http://links.lww.com/EJA/A748 and B, http://links.lww.com/EJA/A749).

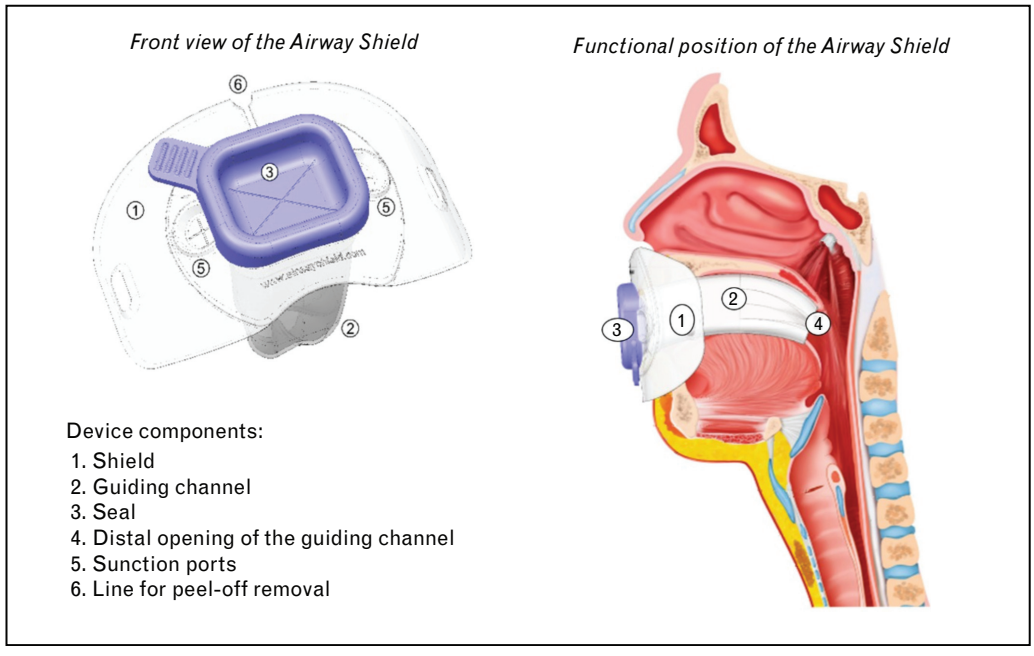
The primary aim of this pilot study was to test the Airway Shield's capacity to reduce exposure to aerosols and droplets in a high-fidelity simulation of endotracheal intubation in a resuscitation manikin model (Megacode Kelly, Laerdal). The secondary outcome was to assess the feasibility of endotracheal intubation with the Airway Shield, measured as first pass success.

The device was tested with two different model setups. To simulate and evaluate the spread of aerosols during the intubation procedure, the manikin was modified by connecting a nebulizer (Aerogen Solo, Aerogen) for inhalation to the reservoir bag of a self-inflating bag connected to the lungs, and powered by a ventilator (Servo U, Maquet), thus permitting the nebulization of an ultraviolet light-sensitive fluid into the simulated airway. Continuous airflow ($6\,l\,min^{-1}$) was applied to the nebulizer to ensure sufficient aerosol visualisation. To simulate and evaluate the spread of droplets, an atomizer connected to a syringe containing coloured fluid (green dye mixed with water) was placed at the level of the manikin's oropharynx, pointing towards the mouth.

Environmental exposure to both aerosols and droplets, with and without the Airway Shield, was measured in two different scenarios – intubation during cardiopulmonary resuscitation, and intubation during oxygenation with high-flow nasal cannula (HFNC). The eight intubations, with and without the Airway shield, were carried out by a single operator. These eight intubations are set out in supplementary table 1, http://links.lww.com/EJA/A761. During the simulations, photographs were taken at a rate of 6 frames per second for three seconds to capture data on the spread of aerosols and droplets at three points in each of the simulated clinical scenarios: just before the introduction of the laryngoscope into the manikin's mouth (corresponding to anaesthetic induction), during laryngoscopy, and during the introduction of the endotracheal tube.

The spread of simulated aerosols and droplets was documented by photographs taken from a fixed angle against a dark background and quantified in pixels. Images from each scenario were selected according to the maximum count of airborne particles in each setting. The detection

Fig. 1 The Airway Shield, a novel barrier device for endotracheal intubation.



and automatic count of pixels (as a surrogate for aerosols and droplets) was carried out using ImageJ v2.1.0/1.53c,[7] an open-source package for the processing and analysis of scientific images (Fig. 2 and Appendix C, http://links.lww.com/EJA/A750). Overall results were expressed as mean ± SD, with the comparison between groups made using a two-tailed Student's *t*-test under the assumption of unequal variances.

In every scenario, first past success was recorded, as well as any operator difficulties which required the performance of any optimisation manoeuvres (including repositioning of the manikin's head, or requiring help from an assistant) while carrying out the procedure. A detailed description of the methods used in the study is provided in the Supplemental Digital Content.

When using the Airway Shield, pixel counts demonstrated a significant overall reduction of aerosols and droplets during intubation in the high-fidelity clinical simulations compared with intubation without the device (mean ± SD: 509 ± 859 vs. 10168 ± 11600; $P = 0.014$). When analysed by subgroups, the Airway Shield reduced the spread of aerosols by 12-fold on average ($P = 0.045$). The spread of droplets was reduced by 43-fold on average with the Airway Shield ($P = 0.14$). Detailed tables, including the count of pixels in each of the three video recording periods during the procedure in each of the scenarios, are provided with our Supplemental Digital Content (Tables 2, http://links.lww.com/EJA/A751 and 3, http://links.lww.com/EJA/A752).

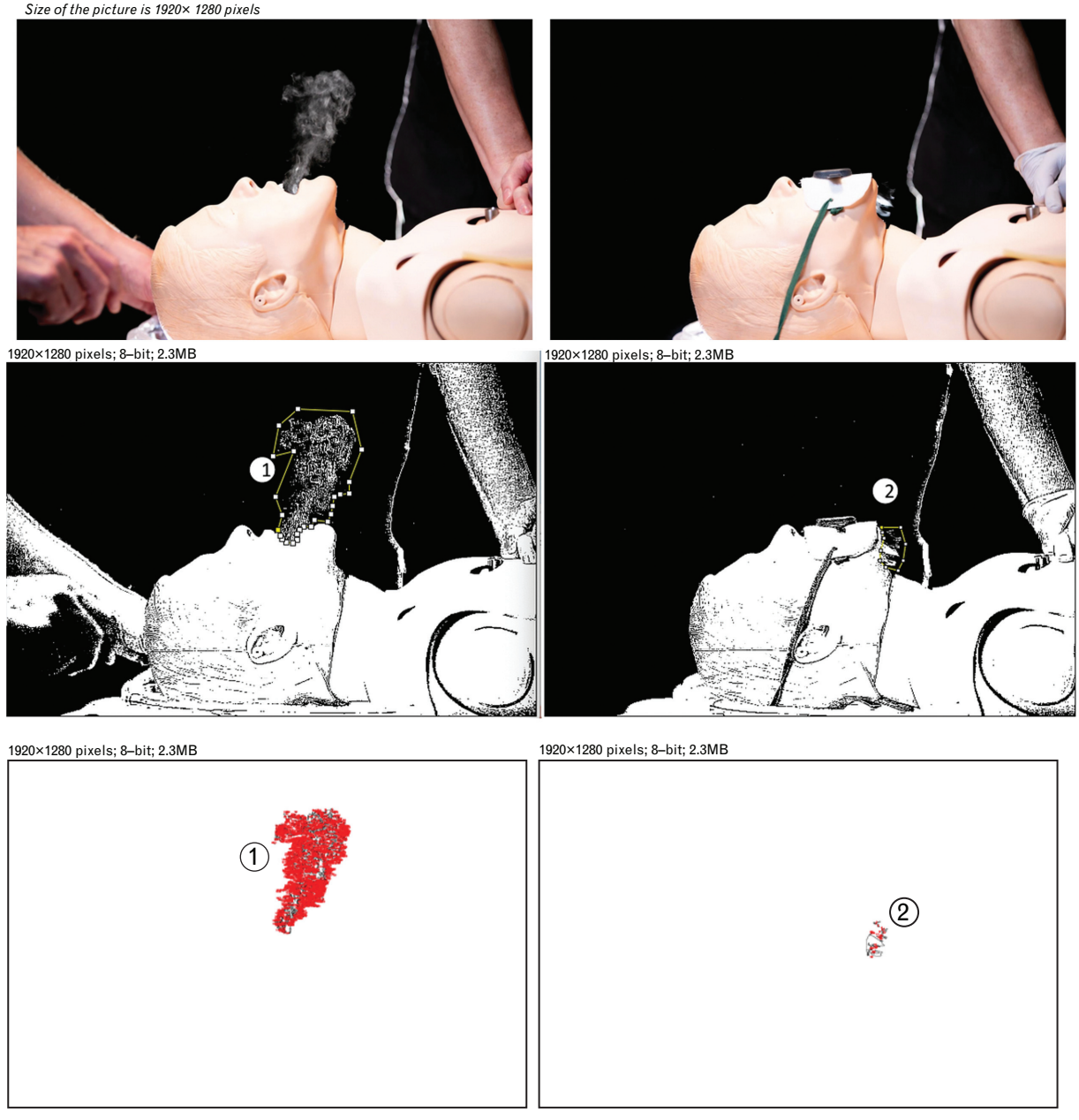
First pass success was achieved in all scenarios, both with and without the Airway Shield. The operator did not describe any difficulty or require any optimisation manoeuvres while carrying out the procedure in any of the simulated intubation scenarios.

This pilot study has four main limitations. First, it is a preclinical study in manikin models using pixel counts as surrogate markers for the aerosols and droplets generated by patients during intubation. Second, it is a single operator. Third, the possibility of small variations in the flow of aerosols and droplets produced by the manikins cannot be excluded. Finally, the number of simulated scenarios is low; however, the variations in aerosol and droplet spread are large enough to permit statistically significant conclusions.

Further studies will need to be performed to evaluate possible airway rescue strategies when using this device, which may include removal of the device for a second attempt at intubation. After intubation, despite the reduction of risk when invasive ventilation is established, removal of the device from the airway will need to be treated as a contaminated procedure, and managed appropriately.

Our study is the first to present a specifically designed mouthpiece which demonstrates effective protection from aerosols and droplets while permitting successful intubation. To our knowledge, this is the first barrier mouthpiece that covers the patient's mouth while allowing endotracheal intubation, as well as being

Fig. 2 Data capture and analysis using ImageJ: measurement of aerosol spread during simulated induction and CPR with and without Airway Shield (scenarios 1.1 and 2.1).



The first row shows the original photographs taken in the scenarios; in the second row the photographs have been converted to black and white to permit the analysis by the software; the third row shows the total area pixelated in each scenario, which was measured by the software. "Count" is the number of areas pixelated detected by the software and "Total area" is the total size of all areas, measured in pixels.

the first device to act as a guiding channel through which the laryngoscope blade and the ETT pass to facilitate the procedure. The results offer a novel perspective on barrier devices and open the door to the possibility of using a mouthpiece to protect healthcare workers from exposure to airborne particles during intubation. Further research is necessary to confirm these findings, including larger simulation studies

and clinical trials to evaluate the safety and efficacy of the Airway Shield.

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Conflicts of interest: JMA has created the concept and design of the Airway Shield and has filed an international patent for commercial use. JL and KS have no conflicts of interest to declare.

Presentations: none.

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Blood pressure targets during general anaesthesia for noncardiac surgery

A systematic review of clinical trials

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Editor,

Observational cohort studies have demonstrated an association between intraoperative hypotension and postoperative complications and mortality. Unfortunately, such observational studies are at a high risk of bias, primarily due to confounding, and it is unclear whether hypotension is causally related to these outcomes. Further, these studies examine the actual blood pressure achieved and not a given blood pressure target. We performed this systematic review to identify clinical trials testing various blood pressure targets during general anaesthesia.

This review was part of a larger review project including clinical trials of adult patients undergoing noncardiac surgery with general anaesthesia. This manuscript focuses on trials assessing various blood pressure targets. Details on the methodology are provided in the protocol and a previous manuscript.[1] We conducted a comprehensive search of PubMed and Embase on March 8, 2021, to identify relevant trials reporting postoperative outcomes.

A total of 13 trials, including a total of 2466 patients, were identified (eFigure 1, http://links.lww.com/EJA/A705, Table 1).[2–14] Given the heterogeneity between the trials, it was not feasible to perform meta-analyses or GRADE evaluation. An overview of the trials is provided in Table 1 and eTable 1, http://links.lww.com/EJA/A705. We chose to describe six outcomes (Table 1), as the remaining outcomes were defined heterogeneously and reported in a limited number of trials (eTable 2, http://links.lww.com/EJA/A705).

Seven trials used preoperative mean or systolic arterial blood pressure to determine individualised targets during anaesthesia.[2–8] These trials generally compared an individualised higher intraoperative blood pressure target to a lower individualised or fixed target (Table 1). Three of the trials reported a difference in the actual measured mean blood pressures of at least 10 mmHg between the groups.[2,7,8] Two trials did not report the achieved blood pressures and two trials did not report a blood pressure difference of at least 10 mmHg (Table 1).[3–6] All trials except one were assessed as having an intermediate risk of bias (eTable 3, http://links.lww.com/EJA/A705).

Two trials reported mortality and three reported hospital length of stay. None reported a difference in these outcomes.[3,5,8] Three trials found a protective effect on delirium of a higher individualised blood pressure target,[5,6,8] whereas one trial found no significant difference.[3] Two other trials reported very few delirium events.[2,4] Two trials reported renal complications. Thompson *et al.* found no significant difference in postoperative creatinine-clearance, whereas Futier *et al.* found a significant difference in renal dysfunction in favor of a higher individualised blood pressure target.[4,5] The same two trials reported cardiac complications and found no difference between groups. Thompson *et al.* and Shapira *et al.* found significantly greater bleeding and transfusion need in the individualised high blood pressure target group, whereas Futier at al. found no significant difference.[4,5,7]