MALAYSIAN HEALTH TECHNOLOGY ASSESSMENT SECTION

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AIRWAY SHIELD

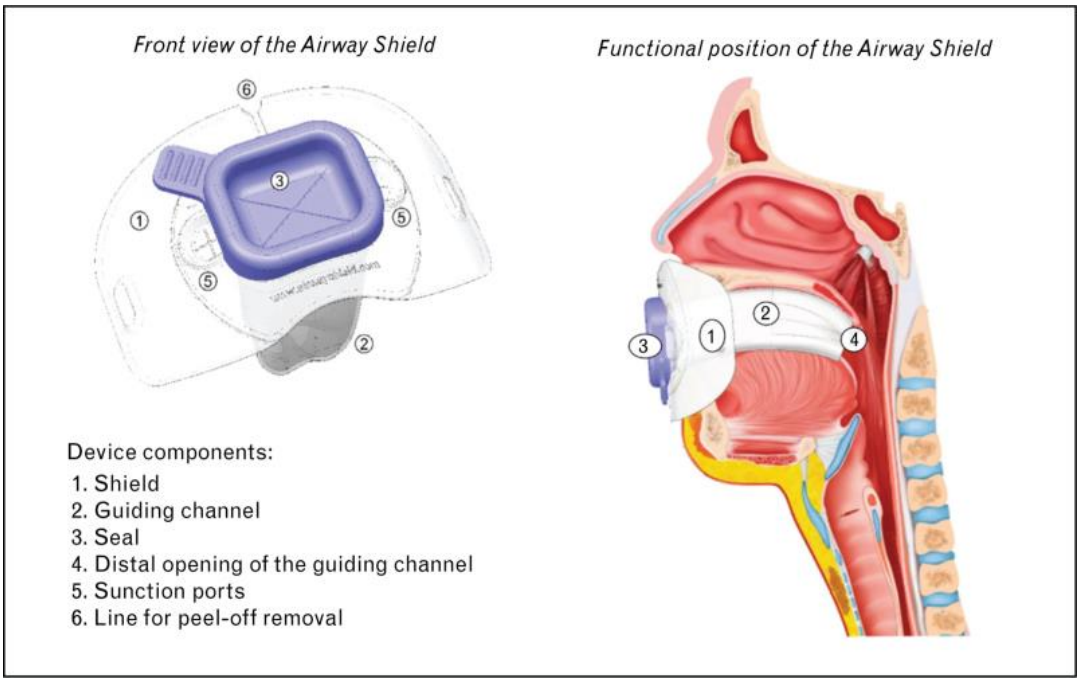
Keywords: endotracheal intubation, airborne disease protection, occupational hazard prevention

SUMMARY OF TECHNOLOGY

Airway Shield, developed by Proxima Clinical Research is a novel barrier mouthpiece to protect clinicians from exposure to airborne particles generated during endotracheal intubation while facilitating the procedure itself, thereby reducing the risk of infections and spread of viruses such as COVID-19.[1,2]

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. It also features two extra channels which permit oropharyngeal aspiration during the procedure. The device is fully disposable and quick and easy to remove, which reduces the risk of transmission during removal.[1]

Figure 1 Airway shield and its functional position in the airway.



Endotracheal intubation with the Airway Shield is performed in three steps as shown in Figure 2. 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.[1]

Figure 2 Intubation steps using Airway Shield[1]

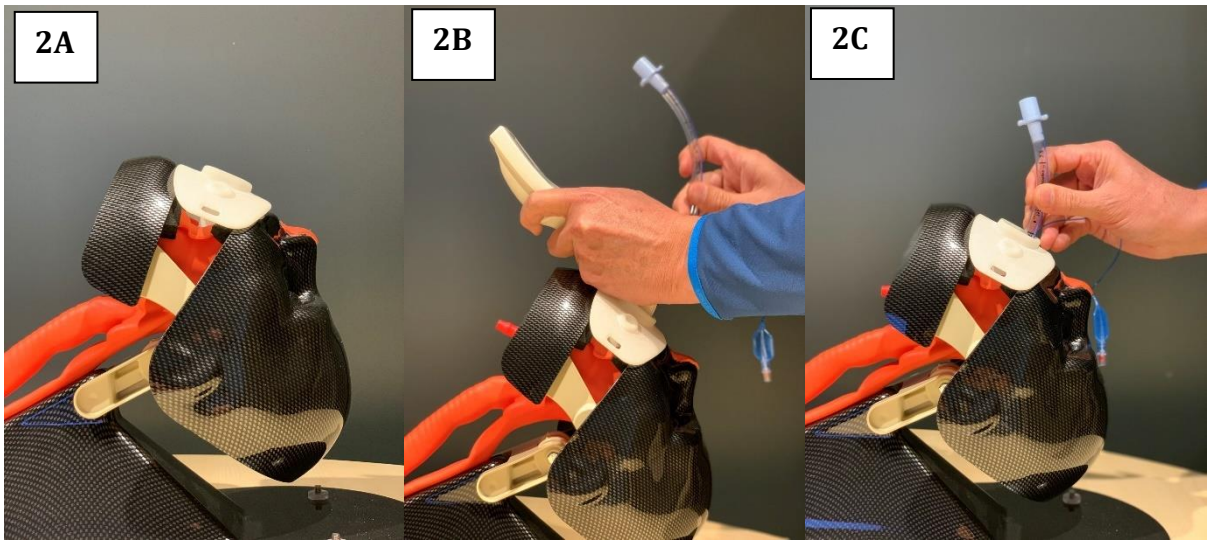


Figure 2A Placing the airway shield: Carefully following the palate, the device is introduced into the mouth until the shield is covering the mouth of the patient. The shield protects the operators from droplets and aerosols. **2B Intubation**: Like in a standard intubation, the video-laryngoscope is introduced first to obtain the view of the larynx, and then the ETT is introduced. The channel of the device facilitates the introduction of the ETT following the blade of the laryngoscope towards the larynx. **2C Removing the Airway Shield™**: Once the ETT is in place and the ventilator is connected, the Airway ShieldTM is peeled away from the midline and removed. The exposure to aerosols and droplets has been minimized.[1]

This technology received Safer Technologies Program ("STeP") Medical Device Designation by US Food and Drug Administration in May 2022; however, it was not marketed as yet.[2]

INNOVATIVENESS

Novel, completely new	/
Incremental improvement of the existing technology	
New indication of an existing technology	

DISEASE BURDEN

Endotracheal intubation is a life-saving procedure and an essential skill performed by multiple medical specialists to secure a patient's airway as well as provide oxygenation and ventilation. There are multiple techniques available, including the visualisation of the vocal cords with a laryngoscope or video laryngoscope, direct placement of the endotracheal tube into the trachea via cricothyrotomy, and fiberoptic visualisation of the vocal cords via the nasal or oral route.[3] In the US annually, 15 million operating room intubations and 650 000 hospital intubations outside the operating room are performed, including 346 000 emergency department (ED) intubations.[4]

Exposure to pathogenic agents is a major occupational risk factor in healthcare facilities. It was long identified that more than 15 airborne infections have been transmitted to healthcare workers (HCW), including tuberculosis, varicella, measles, influenza, and respiratory syncytial virus infection.[5] The increased risk of tuberculosis (TB) infection for HCW is well documented in several studies.[6]

From the recent COVID-19 outbreak, the median HCW infection percentage among total cases in 2020 was 10.04% (range 0–24.09%). South Korea, Hong Kong (China), Iran, India, Egypt and Jamaica had less than 3% HCWs infected among total cases, whereas in Andorra, Brazil, Ireland, Kazakhstan, Philippines, Poland, Slovenia, Spain and Ukraine, the respective percentage was more than 15%. Case fatality could be calculated in 18 regions, with a median value of 0.8% (range 0–18.95%). The maximum case fatality value was observed in Indonesia (18.95%), followed by Uzbekistan (9%), Iran (8.41%), Egypt (6.52%), Philippines (2.83%), Alberta (Canada) (1.29%), Thailand (0.98%), Bangladesh (0.9%), Greece (0.8%), South Korea (0.8%), Italy (0.77%), China (0.67%), the UK (0.61%) and the USA (0.29%).[7]

In Malaysia, the period prevalence of COVID-19 infection and the mortality rate among HCW were 1.03% and 0.0019%, respectively. The majority of infections originated from the workplace (53.3%); a total of 36.3% occurred among staff; a total of 17.0% occurred between patients and staff; and 43.2% originated from the community.[8]

According to one international prospective cohort study in 2020, among 1718 healthcare workers from 503 hospitals in 17 countries reported 5148 tracheal

intubation episodes, the overall incidence laboratory-confirmed COVID-19 diagnosis or new symptoms requiring self-isolation or hospitalisation after a tracheal intubation episode was 10.7% over a median (IQR [range]) follow-up of 32 (18–48 [0–116]) days. The cumulative incidence within 7, 14 and 21 days of the first tracheal intubation episode was 3.6%, 6.1% and 8.5%, respectively.[9]

CURRENT OPTIONS FOR PATIENTS

To improve the safety of healthcare workers during endotracheal intubation in patients in critical care during the COVID-19 pandemic, Malaysian guidelines has highlighted on the usage of personal protective equipment as an essential measure for healthcare workers which includes respiratory protection (N95 respirators or respirators that offer a higher level of protection should be used instead of a facemask when performing or present for an aerosol-generating procedure and usage of Powered Air-Purifying Respirator (PAPR) is recommended if available), eye protection (goggles or face shield), gloves, isolation gown (fluid-repellent long- sleeved gown), head cover, and boot cover/shoe cover (only when anticipating spillage and vomiting). Any airway intervention performed without the proper PPE will endanger the HCW of being infected with the illness. Endotracheal intubation should be done as early as possible to limit aerosol spread. Tracheal intubation and SGA insertion must only be attempted by a skilled individual to achieve first-pass success as multiple attempts will increase the chances of aerosol generation. A cuffed endotracheal tube should be used in this situation to limit aerosol spread. Ensure an adequate cuff pressure to prevent leaks. Video laryngoscopy may reduce the intubator's exposure to aerosolised particles and should be considered if available. If endotracheal intubation is delayed, consider manual ventilation using Bag Mask Ventilation (BMV) with high-efficiency particulate arrestor (HEPA)/Viral filter attached. A supra-glottic airway (SGA) device is preferred if available.[10]

Additionally, other guidelines such as in Poland, some protective barriers such as plastic transparent shield/box, plastic tent or a foil drape might be used to minimize aerosol dispersion during endotracheal intubation.[11]

POTENTIAL IMPACT OF TECHNOLOGY

a. Clinical Impact

Systematic search was conducted from scientific databases such as Medline, EBM Reviews, EMBASE via OVID, PubMed and from the general search engines [Google Scholar and US Food and Drug Administration (US FDA)] on Airway Shield.

There was only one published scientific evidence on effectiveness of Airway Shield.

Efficacy

A pre-clinical study was conducted to evaluate 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, was measured in two different scenarios (intubation during cardiopulmonary resuscitation, and intubation during oxygenation with high-flow nasal cannula). The secondary outcome was to assess the feasibility of endotracheal intubation with the Airway Shield, measured as first pass success. The manikin was modified by connecting a nebuliser for inhalation to the reservoir bag of a self-inflating bag connected to the lungs, and powered by a ventilator, thus permitting the nebulisation of an ultraviolet light-sensitive fluid into the simulated airway. Continuous airflow (6L/min) was applied to the nebuliser to ensure sufficient aerosol visualisation. The eight intubations, with and without the Airway shield, were carried out by a single operator. 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± standard deviation [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), as shown in Figure 3. First pass success was achieved in all scenarios, both with and without the Airway Shield.[12] The limitation of the study is it is pre-clinical, only single operator tested the feasibility and the sample size is small.

Figure 3 Data capture and analysis using ImageJ[12]

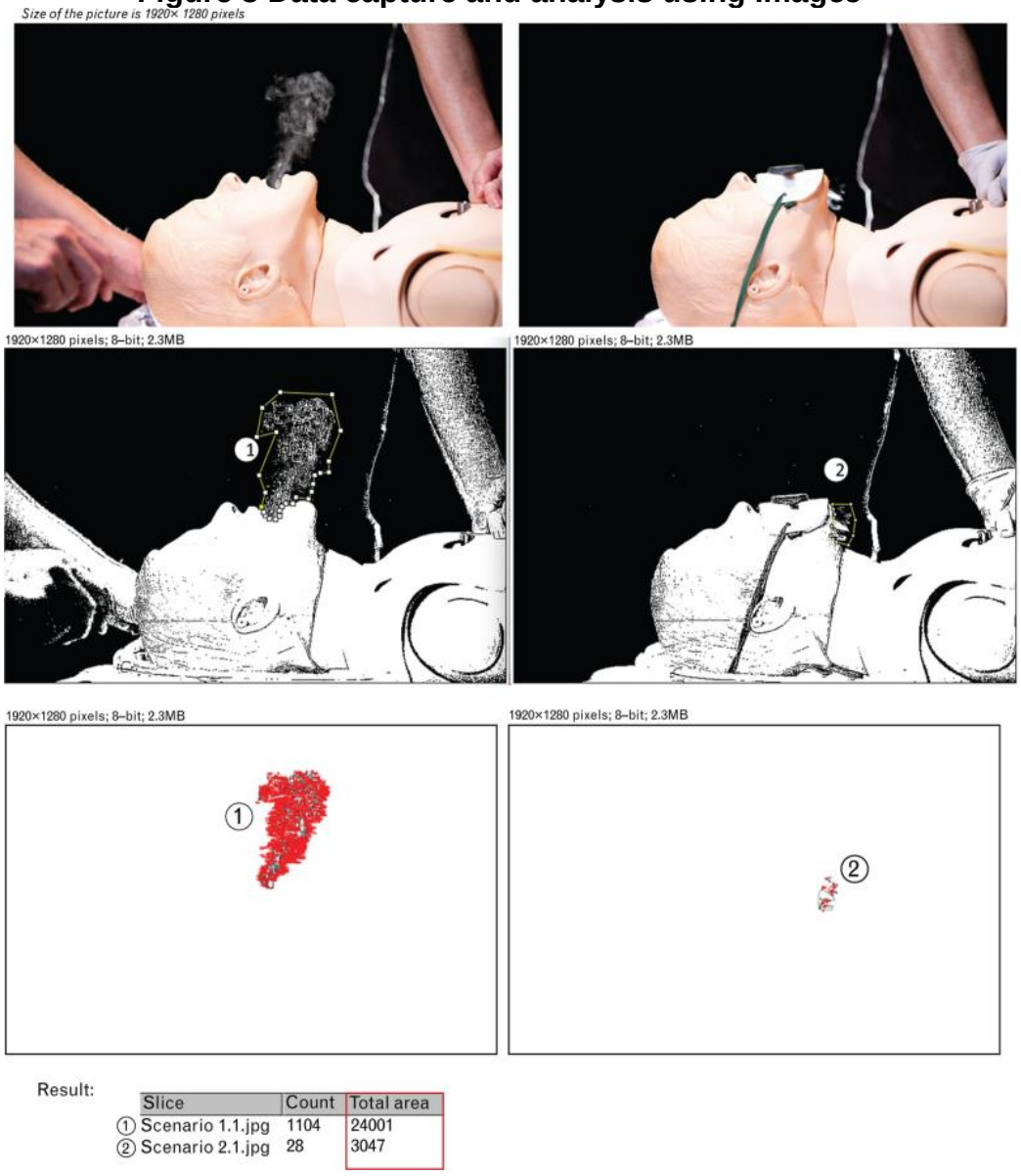


Figure 3 illustrated the measurement of aerosol spread during simulated induction and CPR with and without Airway Shield, showing significant reduction of aerosol spread using Airway Shield.[12]

b. Cost

There was no retrievable evidence on cost or cost-effectiveness study on Airway Shield. Comparatively, the cost for equipment needed for endotracheal intubation are as tabulated below:

Equipment	Cost per unit	In MYR
Disposable gown[13]	$12 (1 USD= 4.67 MYR)	56
N95 respirators[13]	$12	56
Face-mask[13]	$0.55	2.60
Face-shield[14]	$13	60.70

Guedel airway[15]	£4.50 – 5.40 (1£=5.93 MYR)	26.70 – 32.00
Laryngoscope Intubation Kit[16]	$20-25	93.40 -116.70
Video laryngoscope with rechargeable battery[16]	$1200	5601.00

c. Societal/ethical

There was no retrievable evidence on societal or ethical issue on Airway Shield.

d. Safety

There was no retrievable evidence on safety of Airway Shield. However, one major clinical event occurred after intubation of critically ill patients in 45.2% of patients, including cardiovascular instability in 42.6%, severe hypoxaemia in 9.3%, and cardiac arrest in 3.1%.[17] The most frequent problems during endotracheal intubation were excessive cuff pressure requirements (19%), self-extubation (13%) and inability to seal the airway (11%).[18] A defective balloon will result in a loss of ability to protect the airway from aspirate and may make mechanical ventilation difficult. The loss of the universal 15 mm connector (either missing or defective) essentially makes the ETT nonfunctional as the mechanical ventilator or bag-valve-mask cannot interface with it. Some complications from the physical placement of the tube include bleeding, infection, perforation of the oropharynx (especially with the use a rigid stylet), hoarseness (vocal cord injury), damage to teeth/lips, or esophageal placement.[19]

CONCLUSIONS

In conclusion, there was very limited evidence available on Airway Shield and its potential to reduce aerosol spread. However, clinical trial with larger population is recommended to prove its effectiveness in reducing airborne disease spread among healthcare workers.

EVIDENCE

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