Modified full-face snorkel mask: answer to the PPE crisis?

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Summary box

What are the new findings?

- A commercially available full-face snorkel mask can be modified to create a variety of respiratory assisting devices.
- Combining a connector piece and a heat and moisture exchange filter to a full-face snorkel mask can create a reusable piece of respiratory and eye protecting personal protective equipment (PPE).
- Challenges to overcome using this system include carbon dioxide clearance, satisfactory fit and certification testing.
- Additional challenges such as cleaning regimes and unfiltered exhaled air still need to be tackled.

How might it impact on healthcare in the future?

- In an emergency crisis situation, however, this adaptation could prove to be an easily accessible solution for all to have level 2 PPE made available at low cost and rapid production.

INTRODUCTION

The COVID-19 pandemic has brought to light shortages in personal protective equipment (PPE) preparations and supply across the UK. In an emergency, we have all had to adapt to new living and working conditions. As the government moves to relax the lockdown[1] and recommend the use of masks to be worn by the general public, supply problems are likely to continue, hindering the health service. Of particular concern will be the need for adequate protection to allow clinicians to be comfortable in the PPE they are wearing.

There is a definite shortage in supply and clinicians are understandably concerned about this. Two surveys undertaken by the Royal College of Surgeons of 2000 of their members highlighted that over a third of surgeons felt that their Trust did not have adequate PPE, particularly FFP3 masks and full-face visors. Over a quarter of surgeons were not confident that the supplied PPE had been adequately fit tested, with several hospitals around the country removing fit testing altogether instead adopting the fit check alone.[2] Alongside this, 15% felt under pressure to undertake procedures without adequate PPE. BBC Panorama highlighted a worrying lack of preparation from the government in case of a pandemic.[3] Given that this is the starting point for our healthcare system, what has been developed to combat the issue?

METHODS

Adaptation of a commercially available full-face snorkel mask has been raised as a possible solution. As a concept, it would appear a good idea-made of materials that would allow reuse, provides both eye and airway protection and requires only a simple modification to allow connection of a heat and moisture exchange filter by way of traditional manufacturing by moulding, or quicker still, by 3D printing. In essence, this simple change could create a form of protection that could be reusable until the end of the pandemic.

Powered versus non-powered filtration devices have been developed, adapting readily available equipment to create these.[4] The full-face snorkel mask has been identified as an easily modifiable tool to create a variety of respiratory-support devices ranging from dual-patient ventilator use[5] to continuous positive airway pressure and PPE.[6 7]

British Standards and European Regulation takes into consideration additional safety factors that should be considered when designing full-face respiratory protective devices. Similar documents are equally available for masks used for non-aerosol-generating procedures, eye and hearing protection against which PPE products can be tested and certified.

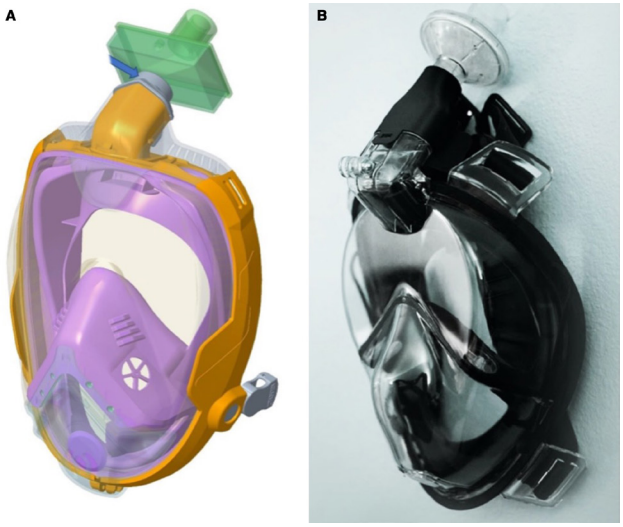

Figure 1 Full-face snorkel mask adaptations with 3D printed connectors for its novel use during the coronavirus pandemic. (A) SEAC's adapted Libera mask. (B) Stanford University's adapted Dolfino mask.

RESULTS

As part of the safety testing of these masks, a quantitative fit test is the gold standard that needs to be passed. Most hospitals will have easy access to qualitative fit testing as is required for FFP3 seal-efficacy testing. However, passing a qualitative fit test for a full-face mask does not make it safe for the user. Despite a successful qualitative fit test suggesting a good seal and protection from inhaling viral particles, the quantitative fit testing of these modified PPE devices has identified a concerning level of carbon dioxide build-up within the mask.[8]

Since this initial finding, different teams have come together across the globe to reassess the science behind this modification with a collaborate team of medics and engineers at Stanford University having successfully designed a modification to the snorkel mask that satisfactorily passes the quantitative testing (figure 1B). SEAC of Italy has managed to go one step further and has successfully achieved a Conformité Européenne (CE) certification of their adapted snorkel mask for use as PPE (figure 1A).

On the strength of this evidence, the Czech Republic has repurposed 25 000 snorkel masks to be given to those who needed it most as a reusable method of PPE.[9]

Figure 1 shows the different masks that have been verified to be safe for use in their alternative form.

Design team	Genova, Italy[10]	Stanford, USA3
Photo	A	B
Mask model	SEAC Libera /Unica	Dolfino
Connector required	3D printed	3D printed
Recommended use	All Aerosol Generating Procedures	All Aerosol Generating Procedures
Highest passed testing standard	Conformité Européenne (CE) marked to standard EN136	In-house quantitative testing passed
Connector material	Polylactic	Formlabs high temperature resin

DISCUSSION

These models that have been successfully adapted to be safe for use have identified a number of key design similarities which contribute to their success. These include

- Single filtered inflow port.
- Outflow ports to remain separate channels ensuring no mixing of inspired and expired gases.
- Maintenance of one-way exhalation valve.
- Standard ISO 22 mm port to attach heat and moisture exchange filter to the connector piece.
- Inert 3D printing material (Formlabs high temperature resin/polylactic).

These designs should ensure that the filter will protect from COVID-19, but the remainder of the system will be safe for the user without risking hypercapnia.

A safe, reusable mask would also require an equally safe cleaning regime. Although one has not been formalised, suggestions have included wiping with 70% ethanol wipes in between uses with submersion in a 50 ppm chlorine solution at the end of the day.[7] Any reusable option will need a suitably verified cleaning regime to ensure safety of the end user.

The full-face snorkel mask adaptation is reliant on a one-way exhalation valve to facilitate adequate carbon dioxide clearance. Unfortunately, this remains the site of unfiltered exhaled air being expelled. Being a product of *personal* protection and not *patient* protection, no current unpowered reusable PPE face mask is able to fulfil both roles. Raising the issue of powered respirators then calls into question issues of supply again and hence is not necessarily a suitable solution in times of supply crises.

Despite the work that is involved, innovators should not be discouraged by these hurdles. Several studies quoted figures between 28% and 85%[11 12] of subjects failing quantitative fit testing with a single respirator model, while others quoted close to 28% failing three different respirators offered.[13] In a study published following the H1N1 pandemic in 2009, nearly 59% of subjects labelled the available respirators as intolerable and non-wearable for extended periods of time.[14] Nearly a decade on, there is not only a shortage during the ongoing pandemic but also a need for a better respirator overall.

CONCLUSION

The reality, therefore, is that there is no one-size-fits-all mask. Innovations around this area should be encouraged and collaboration between engineers, clinicians

and regulators should be encouraged. Together, a suitably safe solution could be created to a problem that is not likely to disappear anytime soon.

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Competing interests A team of authors in Oxford are attempting to pursue a similar adaptation to help with the aforementioned personal protective equipment (PPE) shortages. They have been performing the necessary fit testing and have submitted an option to an independent notification body for the necessary extensive testing in order to be certified as PPE and cleared for safe clinical use. The authors do not recommend its use prior to getting said certifications and write this correspondence purely for informative purposes.

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