ORIGINAL ARTICLE

Preliminary findings of performing aerosol generating procedures using a novel innovative mask in times of COVID-19 pandemic

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ABSTRACT

This article describes an innovative mask consisting of a newly fabricated 3-ply surgical face mask with a custom made attachment consisting of a plastic dome and a one-way valve port that allows endoscopes to be inserted through it. The mask was tested in-vitro with simulated sneezing using fluorescent dyes and also received positive feedbacks from field tests of 30 masks on real users in different hospitals. This innovative mask is useful in providing extra barrier for endoscopic procedures in ENT and can be used beyond this pandemic in patients with other infectious diseases.

INTRODUCTION

COVID-19 infection rates among ENT surgeons are higher compared to other clinicians due to exposure to respiratory aerosols and droplets containing high viral load reservoir during head and neck examinations and endoscopic procedures in the nasal cavity and nasopharynx.[1] This is partly because majority of ENT outpatient procedures involve deep instrumentation that triggers cough reflex where jets of droplets and aerosols generated can reach the healthcare workers, especially those in close proximity, at high volume and velocity.[2]

This article describes an innovative mask, called "One Way Mask™" (1WM), which has been developed since March 2020 by a team of ENT surgeons and engineers, that allows endoscopic examinations to be performed through it.

MATERIALS AND METHODS

The 1WM is a newly fabricated 3-ply surgical face mask by a local mask production company with a custom made attachment consisting of a plastic dome and a one-way valve port (Figure 1). The transparent feature of the dome allows easy visualisation of the patient's nostrils and oral cavity and the flexibility of the dome allows room to manoeuvre different scopes to reach the target area of examination easily. The plastic dome is waterproof and is made of biodegradable material as this is a single-use (disposable) product.

The port is centrally placed to allow easy manoeuvring of the scopes to each nostrils and to the oral cavity. If usage of 70 degree rigid endoscope is required, a gauze can also be pre-placed in the inner surface of the plastic dome before patient wears them, which allows sufficient friction for anterior pulling of patient's tongue from the outside surface of the dome. The port also contains a soft silicone one-way valve that allows endoscopes to be inserted while forming a tight seal around them and closes completely on withdrawal of the endoscopes, therefore prevent leakage of droplets and aerosols throughout the procedure.

The 1WM has been tested in-vitro and with real end-users. To mimic a sneeze producing aerosolisation during endoscopy, 10mls of fluorescent dye was atomized at maximal pressure from behind a plastic model's nasal cavity. The amount of dye deposited on a piece of white PPE (percentage surface area) with and without the 1WM was compared using an ultraviolet light.

The phase 1 of field test on real end users (Figure 2) took place in October 2020 where thirty masks was distributed among four different hospitals to be tried by ENT surgeons for diagnostic endoscopies in ENT departments. A survey in the form of questionnaire (Figure 3) (based on a similar study by Curran et al.),[3] comprised of 9 questions with Likert scores, was also conducted for both ENT surgeons and patients. Based on the feedbacks received, modifications were made to the masks and a phase 2 of field test on real end-users was carried out in January 2021 and is currently still ongoing. The One Way Mask™ has also been filed for patent and industrial design.

RESULTS

There were significant spray of fluorescent dye observed over a significant portion (>80% surface area) of the PPE as well as on the floor and surfaces 200 meters behind the PPE without a mask. On the other hand, in the plastic model wearing the 1WM, all the fluorescent dyes were contained inside the mask with no droplets or aerosols observed on the PPE or in the surrounding.

The Likert scores from the questionnaire from phase 1 of field test revealed a mean score of 4.2 and 4.5 among doctors and patients respectively. Majority of doctors find it easy to insert, withdraw and manoeuvre the endoscopes using this mask and patients have no issues breathing or experience any

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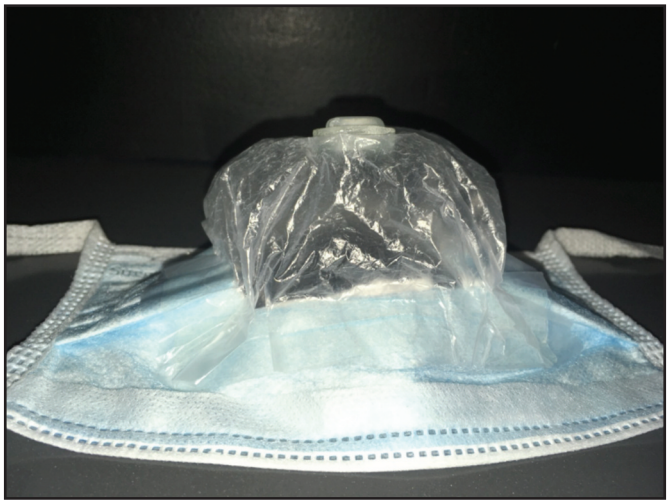

Fig. 1: The One Way Mask™ prototype showing the transparent and flexible plastic dome attachment with a one-way silicone valve port.

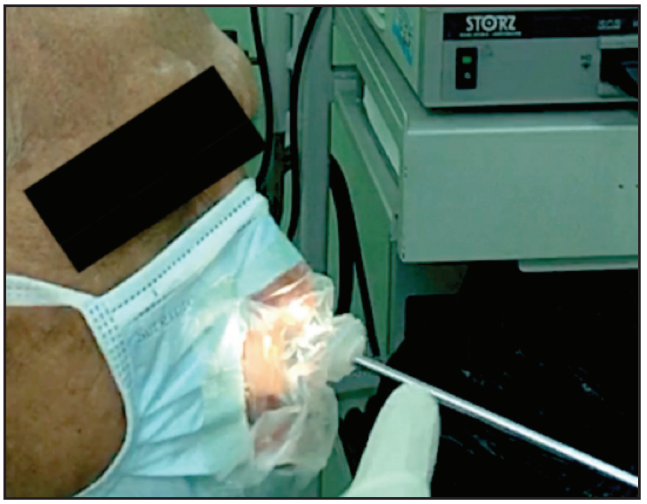

Fig. 2: The One Way Mask™ in use in a clinic.

User Details:

Name:

E-mail:

Job Title: Consultant Specialist MO

Usage Details:

Location of usage: Ward Clinic A&E Others

Scope used: Rigid endoscope (0°) Rigid endoscope (70°) Flexible nasendoscope

Purpose of scope (examination of): Nose Throat Both

Feedbacks:

1-Strongly disagree 2-Disagree 3-Neutral 4-Agree 5-Strongly agree

a) Patients

1. Easy to **put on (tie)** the mask	1	2	3	4	5	N/A
2. Easy to **breathe** while wearing the mask	1	2	3	4	5	N/A

Other comments:

b) Doctors

1) Easy to **insert** scope through the valve?	1	2	3	4	5	N/A
2) Easy to **see** where to move the scope to (nostrils or mouth)?	1	2	3	4	5	N/A
3) Easy to **move** the scope to desired area (nostrils or mouth)?	1	2	3	4	5	N/A
4) Easy to **slide** the scope to examine different areas (nostrils or mouth)?	1	2	3	4	5	N/A
5) Easy to perform **70° rigid scope** with this?	1	2	3	4	5	N/A
6) Easy to **withdraw** the scope after usage?	1	2	3	4	5	N/A
7) Mask **prevented aerosols and droplets** from escaping (if patient sneezed or coughed)?	1	2	3	4	5	N/A

Other comments:

Fig. 3: Questionnaire used during field test with end users.

discomfort when being examined while wearing it. Minor modifications suggested include increasing the size of the dome and usage of softer materials for easier manipulations of endoscopes between nostrils and oral cavity. These changes were made on the prototypes used in phase 2 of field test on real end users.

DISCUSSION

Patients are currently required to either partially or completely remove their masks to allow insertion of endoscopes, where the procedure can inadvertently induce sneezing and coughing. Even if the healthcare workers in close proximity wear adequate PPEs during the procedures, the aerosolised COVID-19 viral particles can remain viable and infectious in the air for at least 3 hours and can also stay on surfaces for up to 72 hours[4] and spread as fomites, where healthcare workers may touch the contaminated surfaces and get infected.[5]

Therefore, it is important for ENT surgeons, innovators and inventors to collaborate and develop strategies to reduce the risks of spread of infection from endoscopic procedures during this pandemic. For example, Workman et al.[6] described using a customised standard surgical mask with a central part replaced with a piece of non-latex glove to allow passage of endoscopes. Other masks innovations include the SNAP (Safe Nasendoscopic Airway Procedure) valved endoscopic port,[5] modified adult endoscopy mask with a 3mm slit,[7] the negative airway respirator made from standard Ambu mask,[8] 3-D printed endoscopy masks9 and usage of an anaesthetic "closed" facemask and DAR connector (L-shaped device with closable hole).[3]

We described another innovative mask in this article that protects clinical staffs as well as the clinical environment to prevent fomite transmission of COVID-19. The mask can also be used not only during the pandemic but also in any infective patients such as patients with Tuberculosis (TB) or during common flu seasons in the future.

Further objective study using laser particle analysis will be carried out during final manufacturing process to assess the bioaerosol cloud pattern generated while using the mask.

CONCLUSION

This article introduced a novel innovative mask with a custom made attachment consisting of a plastic dome and a one-way valve port. Preliminary testing have shown containment of fluorescent droplets and aerosols within the mask with positive feedbacks from end users during first phase of field test. More objective in-vitro testing and second phase of field test is underway to further improve this innovation to provide extra barrier for ENT surgeons during endoscopic procedures.

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