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ORIGINAL RESEARCH

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Patient-worn endoscopy mask to protect against viral transmission

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Abstract

Objectives: To design and evaluate patient-worn personal protective equipment (PPE) that allows providers to perform endoscopy while protecting against droplet and airborne disease transmission.

Study design: Single subject study.

Methods: Mask efficacy was evaluated using a cough simulator that sprays dye visible under ultra-violet light. User-testing was performed on an airway trainer mannequin where each subject performed the endoscopy with and without the mask in random orders. Their time to completion and number of attempts before successful completion were recorded, and each subject was asked to fill out a NASA Task Load Index (TLX) form with respect to their experience.

Results: The mask has a filtration efficiency of 97.31% and eliminated any expelled particles with the cough simulator. Without the mask, a simulated cough is visualized as it progresses away from the cough origin. Subjects who performed trans-nasal endoscopy spent 27.8 ± 8.0 s to visualize the vocal cords for the no mask condition and 28.7 ± 13.6 s for the mask condition (mean ± SD, $p > .05$). There was no statistically significant difference found in the mental demand, physical demand, temporal demand, performance, effort, and frustration of endoscopy under the no mask and mask conditions (all $p > .05$).

Conclusion: The designed PPE provides an effective barrier for viral droplet and airborne transmission while allowing the ability to perform endoscopy with ease.

Level of Evidence: 3 *Laryngoscope*, 2021.

KEYWORDS
airborne, COVID-19, droplet, endoscopic-mask, flu season, personal protective equipment

1 | INTRODUCTION

The risk of viral transmission via droplet and or airborne transmission is exponentially higher in healthcare workers performing aerosol inducing procedures such as nasopharyngoscopy. It has been shown that appropriate personal protective equipment (PPE) leads to effective prevention of respiratory disease transmission, and in particular, the use of masks to filter droplet or aerosolized material is considered essential for effective protection.[1,2] Similarly, it has been shown that transmission of respiratory viral load to a provider may also be reduced with use of

masks by infected patients.[3] Otolaryngology has proven to be one of the highest risk medical specialties in the present SARS-CoV-2 pandemic due to the high viral burden located in the nasal and upper aerodigestive tract with a risk ratio of 2.13, compared to other healthcare workers.[3–6] The earliest reports of physician deaths during this pandemic were related to surgical exposure from otolaryngology procedures.[7]

In the practice of otolaryngology, flexible trans-nasal endoscopy and rigid nasal endoscopy are essential diagnostic and therapeutic procedures. In 2014, Medicare patients alone underwent office based diagnostic laryngoscopy nearly 600,000 times. These endoscopic procedures, and others like it, have potential to become aerosolizing events which increase transmission of viral particles. Aerosolization can occur with a cough, sneeze, gag, or vocalization. Additionally, with more advanced office-based procedures such as nasal debridement, vocal fold injection augmentation, trans-nasal esophagoscopy, or laser ablation in the larynx, aerosolization events are not only inherent to the procedure itself, but also required as part of the laryngotracheal anesthesia preparation. Physicians were discouraged from performing elective endoscopic procedures due to COVID-19 exposure risk.[8] While the impact of this recommendation on clinical practice is unknown, it is feasible that it may have created delays in diagnosis and timely treatment.

Endoscopists typically wear PPE appropriate to the clinical risk, but there is still concern of significant viral transmission due to close proximity to the patient during an aerosolizing event.[9] Similarly, higher room cleaning burden following aerosolizing events increases room turnover times, which further stresses the medical system by reducing service opportunities.[10] To date, there are only a few good options to limit the extent of spread of aerosolization by the patient in the outpatient setting during these types of procedures. One possible approach is reducing the extent of aerosolization of a cough or sneeze by limiting spread, thereby reducing potential for viral transmission.[11–15]

A number of recent studies have begun to study patient worn PPE to assist with transmission reduction during procedures, however to date it is not clear that these devices are applicable to the outpatient setting and have not been tested with flexible endoscopic procedures.[16] Several PPE devices have been displayed in the literature that all create a barrier between the nose and mouth of the patient and the physician, usually in the form of a mask.[16–20] However, most of these solutions lack user-testing to suggest clinical applicability. Here, we present a simple PPE design that can be used for trans-nasal or trans-oral endoscopies, and provide data showing the effectiveness of the PPE and user experience. Such a device must be both clinically effective and not burdensome for successful adoption.

2 | MATERIALS AND METHODS

2.1 | Mask design and manufacturing

A generic mask template was modeled after FDA Emergency Use Authorization (EUA) KN95 masks using Fusion 360 (Autodesk, San Rafael, CA). The model was laser cut on polypropylene sterilization wrap (Halyard, Alpharetta, GA) using a Rabbit Laser Cutter at 20% power and 100% speed (Figure 1A). The mask was heat sealed along the inner edges and elastic bands were stapled on. To create a flexible seal around the nose, 0.1 cm thick Aluminum 1100 sheet was cut into 0.64 cm × 8.89 cm rectangles and adhered onto the mask using double-sided adhesive with the same dimensions. The nose cone was created on Fusion 360 by modeling the center cross-section of the nose cone and

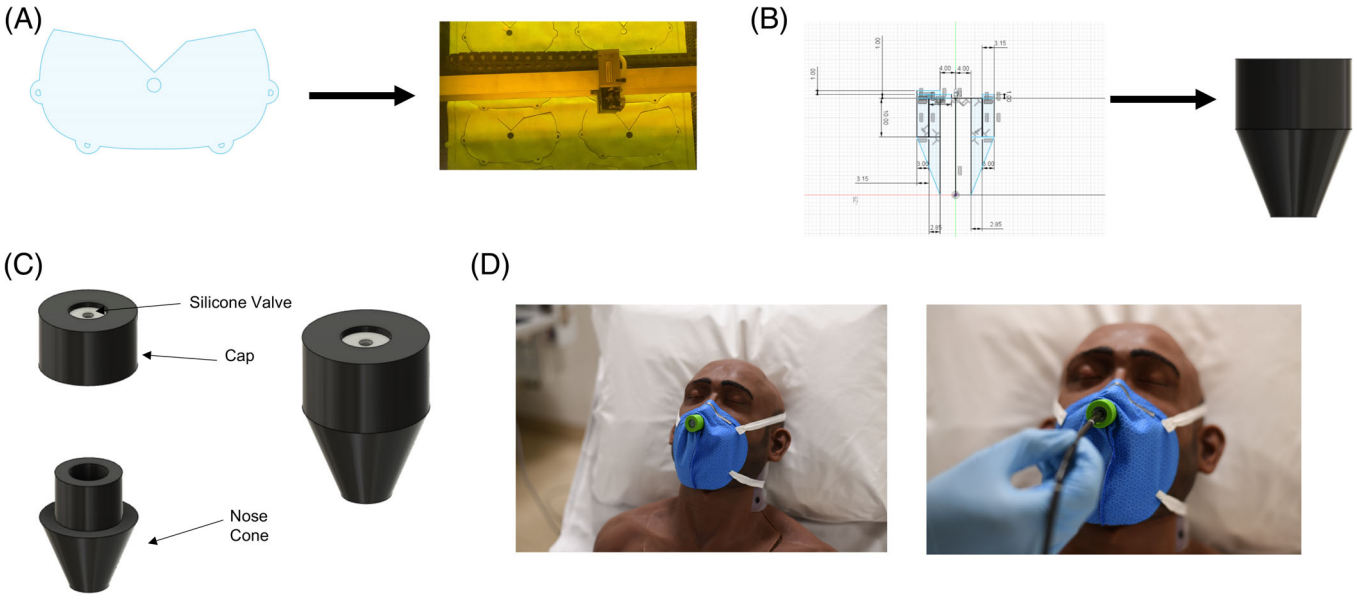

FIGURE 1 Overview of mask design. (A) Schematic showing how a digital version of our mask model and how it is laser cut. (B) Cross-section of the nose cone and the side profile of the 3D nose cone. (C) Schematic showing the nose-cone (black), cap (black), and silicone valve (white) designed for the endoscopic mask is shown from several different angles. (B) The mask is shown on a mannequin both with and without an endoscope in place

rotating it along the central axis to form a 3D object (Figure 1B). Using the Original Prusa i3 MK3S+ 3D Printer (Prusa3D, Prague, Czech Republic), the nose cone components and a mold for the silicone valve were printed. The valve and components of the nose cone were then press fit into the hole at the center of the mask (Figure 1C).

2.2 | Mask material testing

Filtration efficiency of the polypropylene sheet was done using a PortaCount Plus Model 8020 particle counter (TSI, Shoreview, MN). The material is inserted in a chamber that allows room air to pass through the material and enter the PortaCount to read out the number of particles/cc in the air sample. The protocol was modeled after filtration efficiency tests conducted in prior studies found in the literature.[21–25] A HEPA filter that comes with the machine was used as a control. The measured filtration efficiency was then compared to the measured filtration efficiency of 3M 1860 N95 found in literature using the same protocol for measuring filtration efficiency.[24]

2.3 | User-testing in simulation

We deployed a single-subject study design to compare the trans-nasal endoscopy with and without the mask. For comparison, the time to completion, number of attempts before successful endoscopy, and completion of the NASA Task Load Index (TLX) Form were required from each study participant. Participant inclusion criteria included head and neck surgery residents who have been trained in trans-nasal endoscopy. A total of 10 residents were used in the study and served as their own control. Each resident was asked to perform trans-nasal endoscopy on an airway mannequin (7-Sigma, Minneapolis, MN) using a disposable Karl Storz 4 mm flexible endoscope with and without the mask. Timing for each attempt started as soon as the participant inserted the endoscope into the nose (no mask condition) or the silicone valve (masked condition) and ended upon visualization of the vocal cords. After each attempt, the participant filled out the NASA TLX form and rated their mental demand, physical demand, temporal demand, performance, effort, and frustration on a scale of 0–100. Institutional Review Board (IRB) exempt status was given by the UC San Diego IRB for human subjects.

TABLE 1 Measured filtration efficiency of the polypropylene filter material used for the mask and the filtration efficiency of 3M 1860 N95 respirator from literature that used the method

Sample	Polypropylene sterilization wrap	3M N95 1860
Filtration efficiency	97.31 ± 0.32	96.52 ± 1.37[a]

[a]The values are from literature.

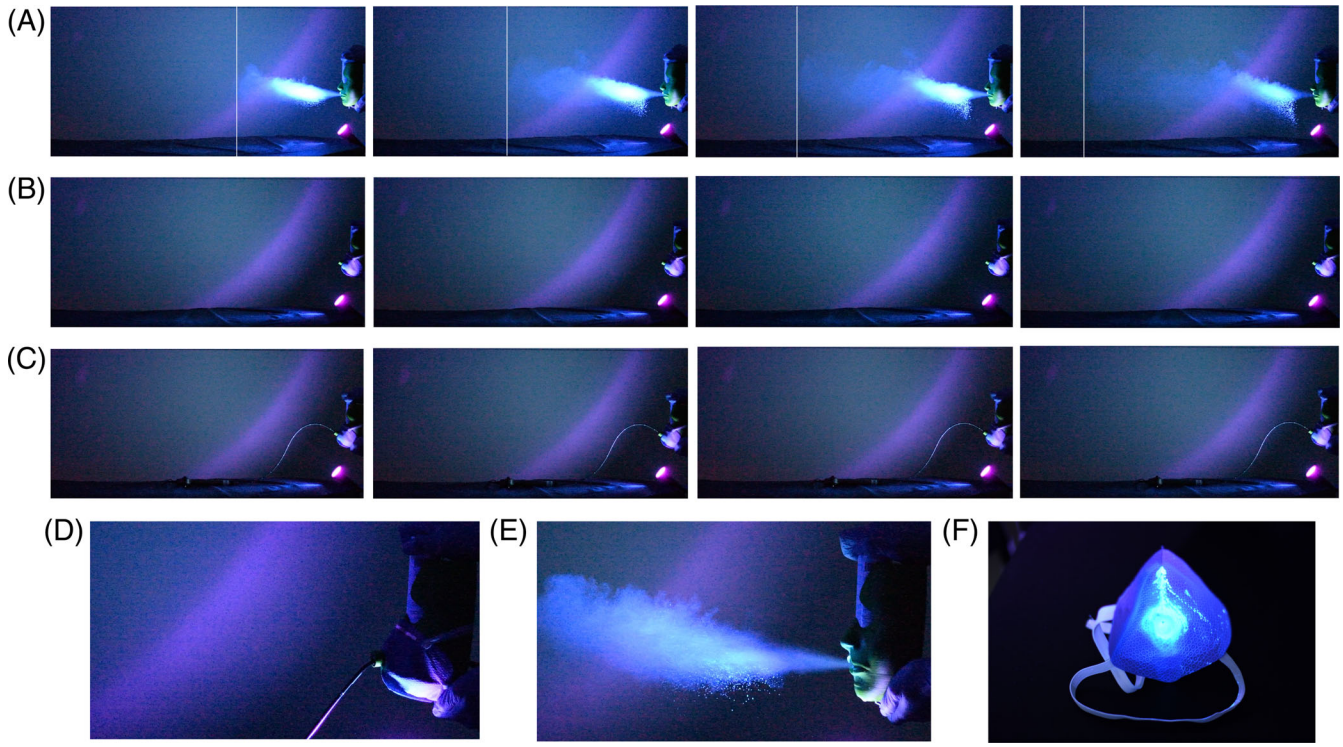

FIGURE 2 Mask containment experiment. (A) Four progressive stills are shown from a single simulated cough in the no mask condition. White lines are added to indicate the end of how far the plume traveled in the still. (B) Four progressive stills are shown from a single simulated cough in the mask without a scope condition. (C) Four progressive stills are shown from a single simulated cough in the mask with a scope condition. (D) Close up still from a simulated cough given in the mask with a scope condition. (E) Close up still from a simulated cough given in the no mask condition. (F) Image showing the inside of the mask after the trials of the mask with a scope condition

TABLE 2 Simulation testing data collected during user testing with both the no mask and mask endoscopy conditions

Metric	Mental demand	Physical demand	Temporal demand	Performance	Effort	Frustration	Total NASA TLX score	Time
Average ± SD (mask)	47.0 ± 25.0	33.5 ± 23.1	44.0 ± 24.0	23.5 ± 20.55	43.5 ± 20.8	18.5 ± 13.6	233.3 ± 59.1	28.7 ± 13.6
Average ± SD (no mask)	48.0 ± 20.7	31.0 ± 19.8	48.0 ± 20.4	18.0 ± 11.4	45.5 ± 22.3	17.0 ± 13.0	229.44 ± 53.58	27.8 ± 8.0
p value	.82	.46	.32	.19	.63	.76	.76	.41

2.4 | Cough simulation experiment

To visual capture the spread of respiratory droplets and aerosol, a cough simulator and viral surrogate used and validated in prior studies was utilized for a cough simulation experiment.[15,16,26–33] Using a tripod mounted Nikon D850 camera with Nikon 50 mm/f1.8 lens simulated coughs were captured at 1080p and 120fps for three conditions: no mask, mask without endoscope, and mask with endoscope (Figure 2A–C). In a simulated hospital room, the 3D printed head was mounted on a stand and contained a pressured canister of GloGermTM MIST. Three trials of three replicate simulated coughs were delivered for each condition. Each simulated cough was made approximately 2 s, and the canister was repressurized after each trial. The speed and 2D max area of the simulated cough falls in the range of a physiological cough as shown in literature.[26]

3 | RESULTS

3.1 | Filtration efficiency

Filtration efficiency of the polypropylene sterilization wrap material used as the filter material for the mask had a measured filtration efficiency of 97.31%. The measured filtration efficiency of 3M N95 1860 found in literature is 96.52% (Table 1).[24,34,35] Both the measured filtration efficiency if the polypropylene sterilization wrap and 3M N95 1860 overlapped within 1 SD. Furthermore, the filtration efficiency was above 95% which is a requirement for any NIOSH approved material that can be classified as N95.[24,34,35]

3.2 | Cough simulation

Three trials of the cough simulation experiment revealed a visualization of cough dispersion for the three conditions: no mask, mask with endoscope, mask without endoscope. The no mask condition shows a large plume of cough progressing away from the mouth with time (Figure 2A). This is not seen in the mask with endoscope and mask without endoscope conditions (Figure 2B,C). Images taken of the inside of the mask after the trials show that the mask material captures the simulated cough inside the mask (Figure 2F). Furthermore, no GloGerm particles were visible under UV outside the mask, further indicating that the mask material contained the simulated cough inside the mask. For the mask with endoscope condition, a close-up image also reveals no visible GloGerm exiting the mask under UV light (Figure 2D,E). The lack of any visible simulated cough exiting the mask or the nose cone for the conditions that use the mask, suggests that the mask can adequately protect a clinician and bystanders during a trans-nasal endoscopy from patients coughing and breathing during the procedure.

3.3 | Mannequin user-testing data

User-testing done with otolaryngology residents showed no difference in time of completion, NASA TLX scores, and the number of attempts for a successful endoscopy. Each participant was able to successfully complete an endoscopy given the study constraints with average times of 27.8 ± 8.0 s for the no mask condition and 28.7 ± 13.6 s for the mask condition (mean ± SD, $p > .05$). Moreover, the ratings reported by each participant for mental demand, physical demand, temporal demand, performance, effort, and frustration had no statistically significant difference between the no mask and mask conditions (Table 2).

4 | DISCUSSION

At the start of the COVID-19 global pandemic, routine procedures that exposed physicians to aerosolization became challenging and less safe to perform. Otolaryngologists have an increased risk of contracting a virus, such as SARS-CoV-2, due to the higher viral load in the nasal and upper respiratory tract. This is especially true for the delta strain which can achieve a 1000-fold higher viral load in the nasopharynx compared to the alpha strain of the first and second waves of the pandemic. Specifically, trans-nasal endoscopy is a procedure that puts endoscopists at risk of contracting COVID-19 because the patient's mouth and nose are exposed during the procedure and events such as coughing and sneezing commonly occur. It is important to note that such risk is also present outside the context of COVID-19 such as during the influenza season and therefore applicability of patient worn PPE extends beyond COVID-19.

Here, we present a potential solution that creates a feasible barrier between the patient and endoscopist while providing a means of safely and easily doing the procedure. The endoscopy mask presented here effectively prevents the spread of aerosolized materials as shown

by the cough simulation experiment. The overall material cost of the silicone, poly-lactic acid 3D printer filament, aluminum alloy, and polypropylene sheets is $0.45, indicating the mask does not pose expense barriers for clinical utilization. Furthermore, user-testing done on a high-fidelity mannequin shows that there is no statistically significant difference in task load and time of procedure between the masked and no mask condition.

More advanced techniques to assess the protective capability of the endoscopic mask are required. Computational fluid dynamic models of masked and unmasked conditions could provide insight into spread of aerosol in 3D space.[36,37] The spread of aerosol and droplets should also be assessed in in real time during a trans-nasal endoscopy using multiple optical particle counters at various locations in the procedure room.[38] These next steps can help to better understand how effective of a barrier the endoscopy mask provides. Lastly, other design modifications to the mask itself could be explored with patient feedback for comfort levels. Such modifications include mask material, mask structure, and nose cone material to name a few.

A number of different patient masks for trans-nasal endoscopic procedures have been developed and tested in various conditions.[39] Specifically for flexible laryngoscopy, Hoffman et al. utilized an acrylic box with sealable ports of differing sizes and required a disposable drape and suction machine with a HEPA filter to create a negative pressure environment around the patient's head. The researcher reported good patient tolerance with nonsignificant changes in pulse oximetry recordings; however, no aerosolization testing was performed.[19] A novel technique described by Narwani et al. utilized an anesthesia face mask with a 5 mm endoscopy port attached to a heat exchanger with a viral filter and demonstrated feasibility of passing a flexible laryngoscope through a 3 mm linear incision of the silicone port cover on a mannequin. However, no further testing was performed.[20] Similar, to our mask design, the majority of the materials used by Narwani et al. are one-time use. One concern for this design would be the need to clean the acrylic container manually with antiseptic wipes, which may have variable decontamination rates. For rigid nasal endoscopy, Khoury et al. utilized a similar system with an anesthesia face mask with a built-in endoscopy port, but modified the mask to attach a suction with a HEPA filter, creating a negative pressure system. Cadaver studies with incense smoke showed this mask system completely removed all visual particles, as compared to an anesthesia face mask without negative pressure and a standard surgical mask.[40] Though similar in particle size, it is unclear if passive incense smoke is an appropriate surrogate for aerosolization events such as coughing and sneezing and whether a digital photo and pixel count is a sensitive enough measure for containment. Workman et al. tested a modified surgical mask with an upper midline surgical glove finger attached to allow placement of a rigid endoscope. Fluorescein was applied to cadaveric nasal cavities and a variety or common surgical techniques were applied, as well as a simulated sneeze. The researchers concluded that aerosol spread was effectively prevented by this mask. However, as they note as study limitations, the study design did not allow for identification of particle size below 30 μm and did not measure the presence of airborne particles.[16] This mask is a relatively inexpensive, one-time use design, reducing the risk of patient-to-patient transmission, but there is concern as to whether it can effectively block aerosolization events without a tight facial seal or fluid barrier.

The COVID-19 pandemic is ongoing and has altered the efficiency and safety of office-based aerodigestive endoscopies by adding time between room use, reducing assisting personnel, and requiring negative pressure operating rooms.[41,42] Thus, a feasible solution as demonstrated by the endoscopy mask should be further evaluated and implemented clinically to improve efficiency and safety for both the current pandemic, as well as future viral endemics.

The results of our study show promise that the endoscopic mask can be used clinically in a disposable manner however, further testing is necessary to prove this. The next steps would include testing the endoscopy mask clinically and assess differences in the task load, time of procedure, and patient comfort between the masked and unmasked conditions. The endoscopy mask poses very little risk to patient safety; however, trials to assess the efficacy of its clinical implementation should be done expeditiously as the benefits far outweigh the risks from a safety, logistics, and financial perspective.

5 | CONCLUSION

The use of the patient worn endoscopy mask presented here provides a protective barrier between endoscopist and patient while maintain a similar user task load as compared to the no mask condition. While more work is required for validation clinically, study thus far is promising, and we propose that this device holds potential given its ease of use, low production cost, and reduced aerosol exposure during procedures.

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CONFLICT OF INTEREST

No conflicts of interest disclosed by any author.

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