The Patient Worn Enhanced Protection Face Shield for Flexible Endoscopy

Running title: Enhanced protection face shield (EPFS) to be worn by the patient during endoscopy

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Jack B Anon : co-owner Aspeus Medical
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Carter Denne: None

CONTRIBUTIONS:
Jack B Anon- study design, conception of device, manuscript writing
Darcy Rees- device design engineering, study design, manuscript editing and review
Carter Denne- device design modification, editing of manuscript

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Abstract

OBJECTIVES: The primary objective of this study was to compare the protection afforded by a standard face shield design to a new enhanced design in a controlled setting.

METHODS: This study was exempted from review by IRB waiver. A flexible fiberoptic endoscopy was placed through stellate openings in the standard face shield and the enhance face shield. A series of simulated coughs were created with bursts of fluorescein dye through an atomizer tip placed within the test subject’s mouth. Ultraviolet lighting illuminated the test area and areas of dye splatter were noted.

RESULTS: Fluorescein dye is easily aerosolized along the lateral inferior aspect of a standard shield with significant contamination of the surrounds. The enhanced face shield maintained a barrier to the aerosolized dye.

DISCUSSION Face shields, rather than face masks, should be considered as a preferred alternative for the public and healthcare professionals (HCPs) alike as they address many of the personal protection (PPE) concerns especially during the Covid-19 pandemic. Otolaryngologists are at high risk from aerosol generating procedures such as flexible fiberoptic endoscopy even when wearing PPE’s. Here we describe a uniquely designed face shield to be worn by the patient as another layer of protection for the environment and medical personnel.
IMPLICATIONS FOR PRACTICE: During the course of a flexible fiberoptic endoscopy, medical personnel are safely isolated from potential infectious particles with a newly designed face shield.
INTRODUCTION:

The Covid-19 (SARS-CoV-2) pandemic has dramatically changed the overall practice of medicine. Currently there is no immunogenic vaccine available and medical therapies are just being explored, making the prevention of infection by SARS-CoV-2 of greatest concern. It is recognized that universal use of face coverings in hospitals and in the community interrupts the transmission of SARS-CoV-2, but concerns about availability, cost, ease of use, comfort, and risks of autoinfection have prevented the healthcare authorities from recommending universal personal protection equipment (PPE) practices.\textsuperscript{1,2} However, it has been suggested that a face shields, rather than face masks, should be considered as a preferred alternative for the public and healthcare professionals (HCPs) alike as they address all of these concerns.\textsuperscript{1,2}

During the Wuhan outbreak, otolaryngologists had the highest rates of nosocomial spread, and anecdotal reports from around the globe appear to support the Chinese experience.\textsuperscript{3-5} It has been suggested that the contact with the upper respiratory mucosa of patients and the high viral load in the upper respiratory tract of SARS-CoV-2 patients could be responsible for exposing otolaryngologists at higher rates than other HCPs.\textsuperscript{3,5}

An area of particular concern are aerosol-generating procedures, such as the performance of flexible fiberoptic laryngoscopy (FFL), and there are currently no formal guidelines to reduce the risk of SARS-CoV-2 virus transmission during these procedures.\textsuperscript{4,3} Additionally, PPE such as masks and gowns can protect the clinician but the examination room environment may be contaminated for hours.\textsuperscript{4,5}
To address this need, we have developed the enhanced protection face shield (EPFS) to be worn by the patient during these procedures. The EPFS is a unique tool that was designed to be worn by the patient during an FFL to address the issues of HCP protection during the procedure and reduce environmental contamination. The EPFS closes the superior opening with a foam strip and limits the lateral opening with an increased horizontal dimension and a strong curve design. The containment is increased further by the inferior opening that is sealed by the addition a lower shelf. Access to the patient’s nose for endoscope placement is accomplished by the placement of a stellate flexible cut opening(s) in the shield at the level of a typical nostril. Here, we demonstrate the ability of the EPFS to protect the HCP and the clinical environment from patient splatter during an FFL procedure.

MATERIALS AND METHODS:
This study is a proof of concept. The Allegheny Health Systems IRB review board granted a waiver for review based on study design. The EPFS is a die cut sheet of 0.012-inch anti fog coated amorphous-polyethylene terephalate (APET) thermal plastic measuring 11 ft by 13 ft in its final form. Further cuts are created along the inferior lateral aspect along with the creation of a dual tab locking system (Figure 1). Two stellate openings are also die cut anteriorly approximating the position of a patient’s nostrils. These openings provide for passage of a rigid or flexible endoscope without violating the shield’s protection. Foam padding attaches along the superior rim of the plastic. Adjustable straps at the top and bottom allow the shield to be fit comfortably. The EPFS is normally stored flat. The integral tabs- when locked into place before use-
form a lower posterior facing ledge. This conformation effectively isolates the lower and lateral edges from the surrounds. (Figure 2)

The efficacy of the EPFS was evaluated in a controlled setting. A “cough” was simulated with the mucosal atomization device (MAD®, Teleflex, Morrisville, NC) attached to intravenous tubing connected to a 20 mL syringe filled with fluorescein dye was placed into the mouth and held at the level of the lips by the teeth (Figure 3). The MAD® tip faced anteriorly and atomizes fluids into a fine mist of particles 30-100 microns in size. An off-the-shelf APET plastic control face shield 0.012 in thickness and 9 in length x 10 in wide attached to a plastic head band was used as a comparator. A stellate cut was also made at the mid portion of this shield for access. The face shields were sequentially placed on the test subject by a medical assistant and a 3 mm fiberoptic endoscope (aScope 4 RhinoLaryngo Slim, AMBU INC, Columbia, MD) was placed through the stellate opening as would occur in an actual endoscopy. For each test, the “cough” consisted of applications of approximately 5-7 mL each of fluorescein dye pushed through the system. Precise localization of the dye of was performed by the activation of fluorescence via a floodlight 100-watt LED UV source emitting at the range of 380-420 nm. Video and high resolution still photography was recorded with two cameras Sony A7iii with Sony FE 28mm F/2 Camera and a Sony A6500 with Tamron 28-75mm F/2.8. (See supplemental video)

RESULTS
Following the test on the standard shield, there is visible fluorescein dye splatter on a number of regions of the face mask (Figure 4). The fluorescein dye was scattered along the side and lower parts of the plastic. More importantly, a field of fluorescein spray was noted across a significant part of the subject’s white shirt. When the EPFS was tested in an identical manner, the fluorescein was captured by the closed lower lateral and inferior part of the shield’s shelf (Figure 5). No fluorescein was observed on the subject’s clothing. The EPFS contained the contaminants within the confines of the closed space around the subject’s face and protected the examining personnel. Close surveillance with the UV light further showed there was no disruption of the shield’s barrier by the endoscope passing through the stellate opening.

DISCUSSION

The aggressive protection of medical personnel, patients, and the community have become issues of paramount importance since the SARS-CoV-2 pandemic revealed flaws in current PPE practices and products.\textsuperscript{1-3} Most procedural considerations from various groups recommend postponing all procedures that are elective or not imminently necessary.\textsuperscript{3-5} This begs the question of how many important, non-SARS-CoV-2 diagnoses could be missed or misdiagnosed and how many patients may experience delayed treatment due to SARS-CoV-2.\textsuperscript{3-5} It is essential that physicians are able to get back to day-to-day patient care while maintaining the health and safety for themselves, other HCPs, and patients.\textsuperscript{2-5} We believe this could be accomplished with other practical PPE options.
There are currently no formal guidelines on the best method of reducing the risk of SARS-CoV-2 transmission during routine use of FFL by otolaryngologists, which has lead our group and others to consider the development of alternative PPE options so that these sensitive procedures can continue. Here we have demonstrated that when the subject is wearing the EPFS, the larger droplets of a simulated cough are captured by the shield’s shelf and not spread beyond the shield’s borders or onto the subject’s clothing. We further showed that there was no disruption of the shield’s barrier by the endoscope passing through the stellate opening. Taken together, these data suggest that the EPFS when worn by the patient during FFL procedures may provide additional protection for the clinician and the clinical environment.

LIMITATIONS OF THE STUDY

The bioaerosol cloud produced from speaking, coughing or sneezing is a complicated system. This multiphase cloud contains particles of gas, liquids and solids. Face shields disrupt the flow pattern from the point source oral cavity and our dye study shows the directional change will lead to a predominant inferior and lateral stream. The MAD device lower limit of droplet production is 30 mm and droplets ≤30 mm are not able to be produced or visualized in our study. Droplets <10 mm have flow patterns similar to that of air flow and are capable of escaping from around the face shield. Similarly, we were constrained by the lack of the availability of laser particle analysis systems and an ability to visualize all particles within the bioaerosol cloud produced by a patient. Our study only gives an overview of larger droplets and further studies are planned to assess the movements of smaller droplets in relation to the shield. Finally, at this time,
all examination rooms that are exposed to patients without (and maybe even with) masks should be considered contaminated. We recommend that appropriate cleaning of these rooms be performed.

CONCLUSIONS

Overall, the multifaceted utility of the EPFS combined with the low cost of $5.00 per unit appears to satisfy some of the many concerns raised by the SARS-CoV-2 outbreak including protection, cost-effectiveness, and supply-chain issues.
References:


Figures:

1. The enhanced face shield demonstrating the design and the tab closure system.

2. The stellate opening allows passage of the flexible endoscope. Note the MAD® nozzle between the lips.

3. Fluorescein dye is present in a 20ml syringe attached via tubing to the MAD®. In preparation to begin a trial run.

4. A standard face shield revealing fluorescent dye has been atomized onto the shield and beyond its boundaries.

5. From within the enhanced shield, dye is present scattered anteriorly, laterally and inferiorly. There is no encroachment through the shield’s barrier, even at the stellate opening.

SUPPLEMENTAL VIDEO; Demonstrates the fluorescein dye study in live demo.
The enhanced face shield demonstrating the design and the tab closure system.

This manuscript has been accepted for publication in Otolaryngology-Head and Neck Surgery.
The stellate opening allows passage of the flexible endoscope. Note the MAD © nozzle between the lips.

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Fluorescein dye is present in a 20ml syringe attached via tubing to the MAD®. In preparation to begin a trial run.

Enhanced Protection Face Shield

MAD in mouth

IV tubing with dye

Syringe with fluorescein

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**Video Clip**
Dr. Anon Face Shield 1_compressed.mp4

This manuscript has been accepted for publication in Otolaryngology-Head and Neck Surgery.
May 8, 2020

To Whom It May Concern:

The project using face shield to limit Ear Nose and Throat professional from COVID-19 would not require review from an IRB as it is not considered to be human subject research.

Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

As this project was to show feasibility of a device, no generalizable knowledge would be obtained.

The IRB does not consider the project to be human subject research and would not be required to review this project.

If you have any questions, please feel free to contact me.

Sincerely,

Dawnmarie DeFazio, CIP, CHSP
Director, Clinical Research and Regulatory Affairs
Vice Chair, AHN Institutional Review Board