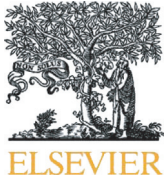




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The pragmatic use of industrial elastomeric facemasks in health care practice during the COVID-19 pandemic

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ABSTRACT

Introduction: The COVID-19 pandemic has forced health care workers to explore alternative personal protective equipment (PPE) strategies due to traditional product shortages in the setting of increased global demand. Some physicians have chosen to use elastomeric face masks (EFMs), traditionally used in non-healthcare industries. **Methods:** We performed a prospective cohort study of Emergency Medicine (EM) physicians working at a Level 1 Trauma Center who chose to use self-supplied EFMs for PPE. All subjects used commercial EFMs with disposable filters (N95, P95, or P100). All subjects chose their mask size independently with no input from employee health regarding appropriate fit. Per study protocol, subjects were fit tested periodically during clinical shifts over the course of the 6-week study period. All investigators performing fit testing underwent OSHA qualitative fit testing training. Data collected included mask/filters age, subjective assessment of mask seal quality, and fit test results. The data were analyzed using descriptive statistics.

Results: 105 fit tests were performed on physicians wearing EFMs over the course of 49 shifts. Physicians felt their fit was adequate for all tests performed. There were no fit test failures in any subjects.

Conclusions: EFMs have an extremely low failure rate. Physicians are able to assess the adequacy of fit and accurately choose EFM size.

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1. Introduction

The COVID-19 pandemic overwhelmed global healthcare resources. Prior to the pandemic, single-use N95 filtering face respirators (FFRs) were the standard personal protective equipment (PPE) against pathogens with aerosol spread, such as COVID-19 [1]. The U.S. Food and Drug Administration (FDA) states that “All FDA-cleared N95 respirators are labeled as ‘single-use,’ disposable devices”, and this is reflected in manufacturer specifications, indicating masks should be discarded after each use [2]. As FFR demand increased simultaneously with disruption of supply chains, FFRs became scarce [3]. In response to this shortage, the FDA issued an Emergency Use Authorization stating that FFRs may be decontaminated and reused, and the CDC endorsed various methods of preserving PPE, including using alternatives to FFRs, including commercial elastomeric face masks (EFMs) [2,4].

EFMs are used in industries to reduce exposure to dusts or aerosols. EFMs are made from flexible polymer materials and have replaceable filters that consist of either N95 or P100 filter media [6]. To date, there have been few assessments of EFM performance in the healthcare setting. In fact, a committee formed by the National Academies of Sciences,

Engineering, and Medicine found no published research evaluating the effectiveness of these devices in the healthcare setting [6]. Based on data from industry use, however, they noted that EFMs have potential to offer higher levels of protection from inhaled pathogens than FFRs of the same filter class [6].

Objectives: Given lack of data and increased reliance upon alternative PPE, we sought to investigate the reliability of EFM via qualitative fit testing in an emergency department (ED) setting.

2. Materials and methods

2.1. Study design

This was an anonymous, cross-sectional, convenience study of physicians who were required to wear a mask of N95 or higher grade who opted to purchase their own EFMs for use in the ED. The study was deemed exempt by the IRB.

2.2. Study setting and population

The study was conducted from April 1 through June 15 at a community-based ED with an annual census of 55 K. Study subjects were emergency physicians (residents and attendings) who were

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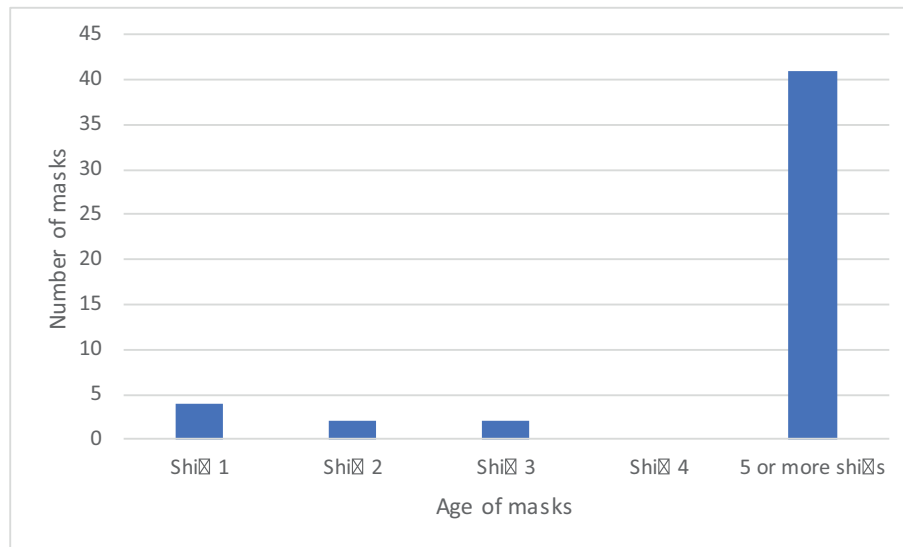


Fig. 1. EFM age by shift numbers in use without changing out filters. A single mask had its filters replaced and was on day 2 of use. This mask is included in the second column.

required to wear a mask of N95 or higher grade continuously throughout their shifts. These physicians opted to purchase their own EFMs rather than rely upon FFRs supplied by the medical center. Shifts were 8–10 h in length. Physicians using Enviro masks, those choosing to use FFRs, and those refusing to participate were excluded.

2.3. Equipment

Physicians purchased and wore a variety of EFMs including 3 M, Honeywell, Rockler, and MSA Advantage brands. Physicians chose the model and size of their EFMs with no input from hospital administration or employee health, and were not fit tested through hospital channels. Therefore, the physicians were responsible for determining adequacy of fit for their own EFMs. All EFMs had disposable filters (N95, P95, and P100).

2.4. Study protocol and measurements

Prior to testing, physicians recorded their impressions of the adequacy of their EFM fit (adequate/inadequate), total number of shifts worn, and any filter changes. Physicians subsequently underwent qualitative fit testing using a standardized hood and 3M FT-32 bitter testing solution. The fit tests were performed per OSHA standards by trained investigators. Fit tests were repeated throughout the shift to assess for EFM failure with extended use. Repeated fit tests were performed at least 2 h apart. Physician level of training and further demographic data were not recorded. Specific EFM size and model were not recorded, as subgroup analysis would not result in statistically relevant conclusions.

2.5. Data analysis and handling

Data were analyzed using descriptive statistics. We intended to analyze data for EFM failure rate as a factor of shifts worn with Fisher Exact. We intended to use Chi Square to assess physician accuracy in prediction of mask failure. All data was analyzed using [VassarStats.net](https://vassarstats.net) (©Richard Lowry 1998–2018).

3. Results

One hundred five fit tests were performed during 49 EM shifts. On average, each EFM was tested twice in any given shift. EFM usage in

number of shifts is recorded in [Fig. 1](#). One mask had undergone a filter change, and the new filter was on its second day of use. That mask is included in the column for “Shift 2.”

There were no quantitative fit test failures in this study, on either initial testing ($n = 49$) or repeat testing ($n = 56$). This was independent of filter or mask age. Physicians performing self-assessment of fit adequacy prior to testing felt universally secure in their mask seal, and were 100% accurate in their assessments.

4. Discussion

This is the first study of EFM failure in a healthcare environment. Our study demonstrated not only that the failure rate of EFMs was 0%, but also that physicians were able to accurately choose appropriate EFMs and assess adequacy of fit independently. Several studies have compared EFM to FFR fit in non-healthcare environments. Using quantitative fit testing, these studies found EFMs to be superior to FFRs in filtering particles in general, as well as with multiple donning and doffings [7–10].

In industry, where there is a significant amount of particulate contamination, filters must be replaced frequently. Because hospital air undergoes filtration, filter lifespan is prolonged, although filter effectiveness lifespan is unknown in this environment. Per investigators at the University of Maryland School of Medicine, filters should be replaced when soiled, wet, or are difficult to breathe through, but can conservatively be used for a year [11]. In a presentation to the National Academies of Science, Engineering, and Medical Committee on the Use of Elastomeric Respirators in Health Care, Heimbuch presented evidence that EFMs could undergo more than 150 cycles of cleaning and disinfecting without affecting failure rates [6].

OSHA recommends that EFMs be cleaned and disinfected as often as necessary [12]. They outline a multistep process including disassembling, soaking in cleaner and then bleach, rinsing and drying. Manufacturers suggest that wipes can be utilized for interim cleaning, but should not be used as the only cleaning method [13]. In a study where EFMs were inoculated with influenza and subsequently cleaned or cleaned and disinfected, no viable virus was able to be cultured from swabs of the EFM regardless of processing method [14]. A study introducing a standard operating procedure for EFM processing demonstrated that users were able to complete processing without errors, but still required 16 min for the process [15]. The same study demonstrated that, over 45 treatments, there was breakdown in some elastic retention straps,

causing stretching of headgear [15]. Removing and reapplying filters may also potentially damage the masks or gaskets, affecting function. Overall, there is probably poor compliance with recommended disinfection procedures. From a survey-based study in an institution with widespread EFM use, only 75% of employees wiped their masks after each use and the majority removed filters and washed the EFM only yearly or never [16].

Our physicians felt very confident in their EFM fit adequacy, similar to other studies. In a survey of workers using FFRs, EFM, and PAPRs, users of EFM rated their sense of protection higher than FFRs [18]. Additionally, after an implementation program of EFM use in an ICU, no healthcare workers chose to return to FFR use when given the option at one month [19].

EFM have potential to not only provide long-lasting protection for the wearer, but also to decrease hospital expenditures. Although EFM are more expensive than FFRs, EFM have a lower recurrent cost over time. In settings such as the medical ICU, a room may be entered anywhere from 43 to 133 times during a 24-h period [19]. Each of these entries equate to one FFR use and subsequent disposal. After implementation of an EFM program, the use of FFRs dropped to zero [19]. Study authors estimated that implementing EFM was 10× less expensive at one month than continued FFR use. There are no studies investigating the decreased costs associated with eliminating warehousing and distribution of FFRs, nor have any studies been performed regarding costs of disinfection and EFM maintenance [6].

Implementation of EFM use is not without challenges. Because staff may rotate locations, mechanisms are needed to transport or store EFM [20]. As mentioned, recommended cleaning and disinfection of masks is cumbersome. Finally, multiple studies have demonstrated that speech intelligibility diminishes with EFM use [21–23].

More research is necessary to compare the effectiveness of various brands and styles of masks in terms of ability to protect, as well as comfort, ease of application and use, and ease of cleaning and disinfection. This information would allow healthcare workers to make informed decisions regarding methods of protection.

5. Limitations

This study was conducted at a single site using convenience sampling. Study participants were not randomized nor were they tested at predetermined time intervals. Donning and doffing procedures were not observed, and may impact fit or function. Likely, some EFM users in our department were not included in the study, whether by choice or due to inconvenience. We also did not record specific mask brand or filter used, nor the methods of cleaning and decontamination.

6. Conclusions

EFMs have a low rate of failure when assessed by standardized fit testing. Physicians are able to independently choose appropriately fitting EFM for clinical use.

Conflicts of interest

There are no conflicts of interest for any of the investigators.

Author contributions

Conceptualization: RJ, DJ, JP, RC, VB, BK
 Methodology: RJ, RC, LR
 Formal analysis: RJ
 Investigation: LR, KM, RC, RJ, VB
 Resources: RJ
 Data curation: RJ, LR, RC

Writing original draft: KM, LR, RJ, DJ, RC, JP

Writing review and editing: RJ, LR, JP, DJ

Visualization: RC

Supervision: RJ

Project administration: RJ

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