

## Concise Communication

# Two masks can be worse than one: N95 respirator failure caused by an overlying face mask

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### Abstract

We have demonstrated the effect of covering an N95 filtering facepiece respirator (FFR) with an overlying face mask. In total, 100 participants successfully completed quantitative fit testing wearing a 3M 1870+ FFR. Among them, 13 (13%; 95% CI, 7%–22%) failed subsequent fit testing when simultaneously wearing a Halyard 47117 procedural mask over the FFR.

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The coronavirus disease 2019 (COVID-19) pandemic caused shortages of personal protective equipment including N95 filtering facepiece respirators (N95 FFR). To mitigate the shortage, the Centers for Disease Control and Prevention, Emergency Care Research Institute, Infectious Diseases Society of America, and others have provided guidance on conservation and modified use of N95 FFRs.<sup>1–3</sup> Modified use can include covering the N95 FFR with an overlying cloth, medical, procedural, or surgical mask (collectively referred to as a face mask) to prevent or reduce FFR contamination. This collective guidance includes permissive statements on covering an N95 FFR with a face mask to prevent or reduce FFR microbial contamination. For example, “HCP can consider using a face shield or surgical face mask over the respirator to reduce contamination of the respirator . . .”<sup>1</sup> Although this idea is intuitively appealing, we found no published evidence demonstrating this presumed benefit.

Covering an N95 FFR with a face mask potentially increases the risk of N95 FFR failure due to induced leakage at the seal between facial skin and the edge of the N95 FFR. The fluid mechanics and seal design principles that provide the theoretical basis for this risk are described elsewhere by the authors.<sup>4</sup> In short, the additional resistance created by an overlying face mask can lead to increased airway pressures that cause leakage at the N95 FFR facial seal.

The severity of COVID-19 and other respiratory infections can be related to the inoculum during exposure. Because N95 FFRs are often worn in high-burden environments (eg, during aerosolizing procedures), N95 FFR failure may result in significant health consequences. Given both community and healthcare use of N95 FFRs, it is imperative that this avoidable risk be recognized and understood. We present experimental data on human participants

to demonstrate that covering a N95 FFR with a procedural mask can lead to a significant rate of N95 FFR failure. This finding augments previously published theoretical evidence and related experimental work.<sup>4–6</sup>

### Methods

#### Population

The study population was drawn from healthcare workers presenting for standard N95 FFR quantitative fit testing conducted by Occupational Health staff at Mayo Clinic in Arizona to determine the acceptability of a 3M 1870+ Aura FFR for clinical use. The final study population consisted of 100 volunteers who achieved a passing result and consented to immediately repeat the test with a Halyard 47117 procedural mask worn over the same N95 FFR. This study was approved by the Mayo Clinic Arizona Institutional Review Board as a nonsignificant risk study requiring oral consent by the participants.

#### Test procedure

Fit testing was completed using the Accufit Pro 9000 following standard procedure. The Accufit Pro 9000 is compliant with Centers for Disease Control and Prevention and American National Standards Institute guidelines. It is a quantitative FFR fit testing device that utilizes particle counting technology to identify inadequate fit with a sensitivity of 0.95 and a specificity of 0.97.<sup>7</sup> Fit testing was performed by having the participant don the 3M Aura 1870+ FFR and adjust the straps and nasal bridge liner to optimize the facial seal. The mask was connected to the Accufit Pro 9000, and employees were instructed to breathe normally and follow standardized instructions. Data were captured during the following activities: normal breathing, moving head from side to side, talking, deep breathing, and moving head up and down.

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**Fig. 1.** Test subject respirator and face-mask configurations.

Results were then processed by the testing device to deliver a final ‘pass’ or ‘fail’ result for the FFR.

Participants who passed the initial FFR evaluation immediately repeated the test with an overlying Halyard face shield 47117 procedural mask. Without removing the original FFR, the procedural mask was placed over the FFR and fit testing was then repeated using the same protocol (Fig. 1). This test sequence mimicked the specific scenario of individuals wearing face masks over previously fit-tested N95 FFRs.

### Analysis

We computed the failure rate with 95% confidence intervals for the fit tests completed with a face mask worn over the N95 FFR. Failure rates by sex were also computed with no significant difference was detected. All analyses were conducted using R software (2019, R Foundation for Statistical Computing, Vienna, Austria).

### Results

In total, 13 study participants (13%, 95% confidence interval [CI], 7%–22%) failed quantitative fit testing when a Halyard face shield 47117 procedural mask was worn over a 3M 1870+ Aura N95 FFR.

### Discussion

In this study, the application of a procedural face mask over an N95 FFR led to FFR fit-testing failure in 13% of participants. This empirical result is consistent with the theoretical physics and engineering model previously reported by the authors.<sup>4</sup> Additional mechanisms such as deformation of the N95 FFR by the overlying face mask could also contribute to N95 FFR failure. The combined empirical results from 2 previously published studies also predict a risk of N95 FFR failure with overlying face masks. Sinkule *et al* demonstrated increased airway pressures when an N95 FFR is covered by a surgical mask.<sup>6</sup> Nelson and Colton<sup>5</sup> showed that increased airway pressures lead to air-purifying respirator leakage. Based on their similar seal configurations, these results suggest that pressure-driven leakage would also occur with N95 FFRs.<sup>5</sup> The combined result of these studies support both our empirical findings and the previously reported theoretical model.<sup>4</sup>

In healthcare settings, specific N95 FFR models are fit tested to ensure an adequate N95 FFR seal. Events or use conditions that degrade the quality of that fit reduce or eliminate the expected protective effect of the FFR. This assertion is underscored by research demonstrating that most particle transmission to an N95 FFR user is through face-seal leakage rather than through the filter medium.<sup>8</sup>

Disposable N95 FFRs are designed, regulated, and marketed for single use. Manufacturers’ user instructions include statements such as “Discard after every use when used for surgical procedures,”<sup>9</sup> and “Fit testing must be performed while the test subject is wearing any applicable safety equipment that may be worn during actual respirator use which could interfere with respirator fit.”<sup>10</sup> The latter statement indicates that an individual’s N95 FFR fit-testing result is valid only for the actual test conditions. Thus, adding an overlying face mask later invalidates test results obtained when the overlying face mask was not in place.

Our study had several limitations. It was conducted at a single institution. A single type of fit-testing device was utilized and a single specific N95 FFR and procedural mask combination was tested. The results may not be applicable to other combinations of N95 FFRs and face masks. The binary pass–fail results of standard employee or occupational health testing are reported; actual measured leakage flow rates were not available. The reproducibility of standard occupational health quantitative fit testing was not verified by performing repeat testing without a covering face mask in place. The clinical impact of the measured increased failure rate is unknown.

In conclusion, this study demonstrated that covering N95 FFRs with a face mask can cause N95 FFR failure. Generic guidance on the use of N95 FFRs should consider the potential risk of increased failure when they are worn with an overlying face mask. Further research to verify the results with our and other FFR–face-mask combinations is needed.

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