Quantitative form and fit of N95 filtering facepiece respirators are retained after dry and humid heat treatments for coronavirus deactivation

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Summary
Re-use of filtering facepiece respirators (FFRs, or commonly referred to as N95s) normally meant for single use only is becoming common in healthcare facilities due to shortages caused by the COVID19 pandemic. Here, we report the results of quantitative fit tests of FFRs after heat treatments at 75 °C both under dry and humid (90% relative humidity) conditions. These conditions have been previously reported to deactivate coronaviruses (including SARS-CoV-2) while maintaining filter efficiency. FFRs passed quantitative fit tests after undergoing both single and ten heating cycles in both dry and humid conditions. These results suggest that thermal deactivation of coronaviruses is a potentially rapid and widely deployable method to re-use N95 FFRs in emergency situations where re-using masks is a necessity and broad-spectrum sterilization is unavailable.

Introduction
The worldwide global demand for N95 filtering face respirators (FFRs) for healthcare professionals will quickly outpace supply as the global COVID19 pandemic continues. Several protocols for disinfecting and reusing FFRs that are normally for one-time use only have been proposed and the FDA has authorized emergency use of vapor hydrogen peroxide (VHP) as a broad-spectrum sterilant for re-use of FFRs.

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1 See summary on the CDC website, https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/decontamination-reuse-respirators.html (retrieved 4/14/20)
2 For examples, see FDA letter to STERIS Corporation, https://www.fda.gov/media/136843/download and FDA letter to Battelle Memorial Institute, https://www.fda.gov/media/136529/download (retrieved 4/14/20)
FFRs have two modes of protection. First, the polypropylene filter element inside the mask must efficiently capture aerosolized particles. Second, the FFR must form a good seal around the nose and face of the wearer. While several decontamination methods have been reported to maintain the filter efficiency of FFRs, there are few reports on the quality of the seal via quantitative fit testing of FFRs following decontamination protocols. A recent evaluation of typical hospital decontamination protocols showed that quantitative fit was retained following multiple cycles of ethylene oxide, VHP, and (for some FFR models) autoclaving.³ Quantitative fit testing of heat treatment at 75 °C has not yet been reported.

Because VHP requires centralized operations and specialized equipment, it may not be available in all emergency situations. In this study, we report that the form and the fit of N95 FFRs, as measured by quantitative fit testing, are retained following heat treatments at 75 °C for 30 minutes both with and without humidity. Although this temperature is not a broad-spectrum sterilant, previous studies have reported SARS-CoV-1 deactivation at 60 °C/30 minutes (≥log 5 reduction in viral activity)⁴ and at 75 °C/15 minutes (≥log 4 reduction).⁵ Most recently, SARS-CoV-2 has been shown to be deactivated (≥log 6.8 reduction) by heating to 70 °C for as little as 5 minutes.⁶ Filter efficiency of FFRs has been reported to be maintained after 90 °C under dry heat for 1 hour.⁷ A very recent report found that filter efficiency of meltblown filter fabric was not affected by either dry or moist heat at 75 °C.⁸ Therefore, the heating schedule used in this study is hot enough to deactivate coronaviruses but cool enough to maintain the filter efficiency of the FFR.

Method

Heat treatments

Prior to heat treatment, a volunteer participant briefly fitted a new, unused FFR (3M Model 8210) to their face and nose structure to simulate a first-time use. FFRs were then loaded into a sterilization pouch (CrossTex Sure-Check, SCL12182).

³ Kumar, et. al., MedRxiv pre-print, https://doi.org/10.1101/2020.04.05.20049346
⁴ Rabenau, et. al., Medical Microbiology and Immunology, 194, 1 (2005)
⁵ Darnell, et. al., Journal of Virological Methods, 121, 85 (2004)
⁶ Chin, et. al., The Lancet Microbe, in press (2020), https://doi.org/10.1016/S2666-5247(20)30003-3
⁷ Viscusi, et. al., The Annals of Occupational Hygiene, 53, 815 (2009)
⁸ Liao, et. al., MedRxiv pre-print, https://doi.org/10.1101/2020.04.01.20050443
For dry heating, the FFRs were loaded into an oven (Cascade Tek TFO-1) pre-warmed to 75 °C and operating at ambient humidity. We estimate that ambient humidity at 75 °C is <5% relative humidity. The oven door was held open for <30 seconds during loading and experienced a temperature loss of <2 °C. Some FFRs were instrumented with a thermocouple as shown in Figure 1a to monitor the thermal history. Figure 1b shows the thermal history of several FFRs from both the top and bottom shelf of the oven. The FFRs heated to 75 °C in approximately 5 minutes and this temperature was maintained to ±3 °C throughout the 30-minute treatment. FFRs that were subjected to multiple cycles were allowed to cool to room temperature but not removed from the pouch prior to the next heating cycle.

For humid heating, FFRs were loaded into an environmental chamber (Espec SH-242). We visually confirmed that the pouch allowed steam to permeate to the surface of the FFR during experimental process development. The chamber was programmed to ramp over 15 minutes to 75 °C and 90% relative humidity, hold those conditions for 30 minutes, and ramp back down to room temperature and humidity over 15 minutes. For FFRs treated for multiple cycles, these conditions were held for seven hours before the next heat and humidity cycle began.

Neither oven used has any exposed heating elements, as the infrared radiation emitted from exposed heating elements will be absorbed by the polymer components of the FFR and cause rapid heating and damage to the FFR.

![Figure 1: a) Thermocouple attached to an FFR with Kapton tape. This picture shows a 3M Model 8511 N95 FFR used for validating the process. All fit tests were performed with a 3M Model 8210 N95 FFR. b) Thermal history of FFRs on top (blue) and bottom (red) shelf of oven over multiple cycles.](image-url)
Quantitative fit test

Quantitative fit tests were performed per OSHA fit test protocol 1910.134, Appendix A using a TSI PortaCount Respirator Fit Tester 8038 (TSI Instruments, Shoreview MN). This instrument does not test the effectiveness of the filter, which previous studies have validated up to 90 °C. The tests performed in this study quantify changes to the sealing surface. The passing criteria for the fit test was a quantitative fit factor of 100, which is the OSHA criteria for new, unused FFRs.

A sodium chloride (NaCl) aerosol generator and two humidifiers with tunable droplet size were used to achieve background levels of aerosol. The PortaCount Fit Tester 8038 uses a pre-selector to ensure that the detected aerosols reflect those penetrating the sealing surfaces and not the filter itself. Aerosolized particle counts were compared inside and outside the mask while the participant performed a series of seven 60-second and one 15-second breathing, movement, and speaking exercises including:

- Normal breathing
- Deep breathing
- Head side-to-side
- Head up and down
- Talking
- Grimacing (15 seconds)
- Bending over/reaching down
- Normal breathing

FFRs were only fit-tested on the volunteer who originally donned and doffed the mask prior to the heat treatment. Fit tests on masks 01-08 (Volunteer A) were performed sequentially, but the order of fit tests on masks 09-16 (Volunteer B) was randomized.

A total of 18 FFRs were treated in this study as shown in Table 1. For each heating schedule tested, the samples were cycled either once or ten times. Because the fit test is destructive so pre- and post-treatment measurements were not possible on the same mask. Instead, control measurements were made with new, unused FFRs without heat treatment for each volunteer.

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[9] https://www.osha.gov/laws-reggs/regulations/standardnumber/1910/1910.134AppA (retrieved 4/14/20)
Table 1: Sample set of FFRs and conditions tested in this study.

| Sample          | Humidity | Heating cycles | Volunteer |
|-----------------|----------|----------------|-----------|
| 01, 02, 03, 04  | Dry      | 1x             | A         |
| 05, 06, 07, 08  | Dry      | 10x            | A         |
| 17 (control)    | N/A      | None           | A         |
| 09, 10, 11, 12  | 90% RH   | 1x             | B         |
| 13, 14, 15, 16  | 90% RH   | 10x            | B         |
| 18 (control)    | N/A      | None           | B         |

Results and discussion

Results of the quantitative fit tests are shown in Table 2. A passing score is 100, and the maximum possible score is 200.

None of the processed samples showed any qualitative change in feel or appearance. One of the elastic straps on sample 05 snapped upon doffing the FFR after passing the quantitative fit test.

All samples subjected to dry heat cycles passed the quantitative fit tests with a fit factor of >100. After one heating cycle there was no significant change to the quantitative fit test result for the four tested samples. After 10 cycles all four tested samples had the maximum score upon fit testing. Due to FFRs 01-08 being tested sequentially, we are unable to disambiguate whether the improvement in quantitative fit test results for masks treated for ten cycles versus one cycle is due to the heat treatment or an improvement in donning procedure over time.

Likewise, all samples subjected to moist heat cycles passed the quantitative fit tests with a fit factor >100. There was no significant change to the quantitative fit test result for the eight samples tested, nor a correlation between score and number of treatment cycles.

No significant difference was observed between the two volunteers.
Table 2: Results of quantitative fit tests

| Sample | Humidity | Heating cycles | Volunteer | Fit factor  |
|--------|----------|----------------|-----------|-------------|
| 01     | Ambient  | 1x             | A         | 107 (pass)  |
| 02     | Ambient  | 1x             | A         | 195 (pass)  |
| 03     | Ambient  | 1x             | A         | 165 (pass)  |
| 04     | Ambient  | 1x             | A         | 149 (pass)  |
| 05     | Ambient  | 10x            | A         | 200+ (pass)*|
| 06     | Ambient  | 10x            | A         | 200+ (pass) |
| 07     | Ambient  | 10x            | A         | 200+ (pass) |
| 08     | Ambient  | 10x            | A         | 200+ (pass) |
| 09     | 90% RH   | 1x             | B         | 200+ (pass) |
| 10     | 90% RH   | 1x             | B         | 163 (pass)  |
| 11     | 90% RH   | 1x             | B         | 200+ (pass) |
| 12     | 90% RH   | 10x            | B         | 200+ (pass) |
| 13     | 90% RH   | 10x            | B         | 200+ (pass) |
| 14     | 90% RH   | 10x            | B         | 200+ (pass) |
| 15     | 90% RH   | 10x            | B         | 200+ (pass) |
| 16     | 90% RH   | 10x            | B         | 161 (pass)  |
| 18     | N/A      | None           | B         | 200+ (pass) |
| 17 (control) | N/A   | None           | A         | 181 (pass)  |

* Strap broke upon doffing
In our initial experiments, we attempted to heat an FFR in an oven with an exposed heating element. We found that the FFR heated rapidly and showed visible signs of softening and melting. We believe this is due to the infrared radiation emitted by heating elements, which typically operate at temperatures of ~800-1000 °C. Polymers strongly absorb blackbody radiation (2-3 μm wavelength) emitted by the heating elements at this temperature. We therefore caution against using any heating method which exposes the FFR directly to radiation from the heat source.

Conclusion
We subjected N95 FFRs to one and ten heating cycles up to 75 °C under dry and humid (90% relative humidity) conditions. Quantitative fit testing did not show any degradation in the fit factor, showing that the form and fit of these FFRs was retained following the heat treatments. These temperatures and times have already been shown to deactivate coronaviruses (including SARS-CoV-2) in liquid media, although inactivation measurements for virus on filter material itself have not yet been reported to our knowledge. These temperatures have also been shown not to negatively impact filter efficiency and airflow of melt-blown propylene filter elements found in N95 FFRs.

The emerging evidence shows that heat treatments may be used as an effective method for re-using N95 FFRs. It should be noted that heat treatment is not a broad-spectrum sterilant and that N95 FFRs are normally meant for one-time use. However, in emergency situations heat treatments specifically to deactivate coronaviruses may be developed using commonly available equipment (incubators, blanket warmers, clothes dryers, ovens, etc.). Heat treatments may therefore serve as a rapid method for re-use of FFRs in areas where FFRs are in critically short supply, specialized decontamination equipment (e.g., VHP) is not available, and surface sterilization (e.g., ultraviolet germicidal irradiation (UVGI)) is insufficient.

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