Is the Current N95 Respirator Filtration Efficiency Test Sufficient for Evaluating Protection Against Submicrometer Particles Containing SARS-CoV-2?

Changjie Cai1,*, Evan L. Floyd1, Kathleen A. Aithinne1, Toluwanimi Oni1

1Department of Occupational and Environmental Health, University of Oklahoma Health Sciences Center, University of Oklahoma, Oklahoma City, Oklahoma 73104, USA

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Abstract

Previous researchers measured the Overall Filtration Efficiency using sodium chloride testing aerosol with aerosol photometer to analyze the reuse of respirators after sterilization. However, this study showed that the Overall Filtration Efficiency would significantly overestimate the respirators’ ability to protect against submicrometer particles containing SARS-CoV-2. For example, after three cycle H2O2 vaporous sterilizations, the most penetrating particle size for the N95 level respirators was from 250 nm – 500 nm, which carried the peak concentration of the SARS-CoV-2 in hospitals. The Size Specific Filtration Efficiency (250 nm – 500 nm) dropped to 56%±4%, however, the Overall Filtration Efficiency was still 86%±5%. In order to protect health care personnel adequately, we recommend measuring the Size Specific Filtration Efficiency to evaluate the reuse of respirators.

NOTE: This preprint reports new research that has not been certified by peer review and should not be used to guide clinical practice.
Keywords: N95, Size Specific Filtration Efficiency, Overall Filtration Efficiency, Submicrometer Particles, SARS-CoV-2

Introduction

Recent studies indicate that aerosol transmission of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is plausible since the virus can remain viable and infectious in aerosol form for hours (1,2). The actual SARS-CoV-2 size ranges from 60 nm – 150 nm (3,4,5). The peak concentration of the SARS-CoV-2 in hospitals was found in 250 nm – 500 nm particles (6). Due to the COVID-19 pandemic and shortage of mask supplies (7), some studies analyzed the reuse of N95/KN95 masks after sterilization by measuring the filtration efficiency using sodium chloride (NaCl) test aerosol (8,9). The N95 grade mask should have a minimum filtration efficiency of 95% for 300 nm NaCl aerosols. The light-scattering instruments (e.g., aerosol photometer), which are commonly used for filtration efficiency test, are usually limited to measuring aerosol size from 100 nm to 10 µm. However, the count median diameter of the NaCl test aerosol is 75±20 nm with the geometric standard deviation ≤1.86 from the U.S. Centers for Disease Control and Prevention (CDC) National Institute of Occupational Safety and Health (NIOSH) procedure No. TEB-APR-STP-0059, meaning around 97.4% particles are ≤250 nm, and around 92.4% particles are from 100 nm – 250 nm, which is not in the particle size range of containing the peak concentration of the SARS-CoV-2 in hospitals. Therefore, a mask efficient for particles ≤ 250 nm may not capture most SARS-CoV-2, and the size specific filtration efficiency is a
better assessment of the mask’s protection ability rather than the overall filtration efficiency
to prevent the SARS-CoV-2 transmit via airborne particles. The goal of this demonstration
study was to test the effects of multiple sterilization cycles on the size specific filtration
efficiency compared to the overall filtration efficiency of KN95 and N95 masks.

Methods

We compared the effects of two- and three-cycle sterilization using vaporous
hydrogen peroxide (H₂O₂) and ultraviolet (UV) germicidal irradiation on the filtration
efficiencies by size of KN95 (Civilian Antivirus, Qingdao, Shandong, China) and N95
(model 1860, 3M, St Paul, MN, USA) mask. The experimental setup was illustrated in
previous study (10). A NaCl aerosol was generated using a Collision Nebulizer (3 jet, CH
Technologies, Westwood, NJ, USA) operated at 20 psi using 2% NaCl recommended by
NIOSH procedure No. TEB-APR-STP-0059. We tested five samples for each mask. A
scanning mobility particle sizer (SMPS, model 3936, TSI Inc., Shoreview, MN, USA) was
used to measure the number concentration of test aerosol from 16.8 nm to 514 nm up and
down stream of each sample. We conducted a two-sample t-test (with α=0.05 as significance
threshold) to compare the mean filtration efficiency of the five samples at each aerosol size
between two and three sterilization cycles.

Results

The effects of multi-cycle sterilization on the filtration efficiency by aerosol size are
summarized in the Figure 1. After three H₂O₂ sterilization cycles, the filtration efficiency for 250 nm – 500 nm particles dropped from 84%±2% to 68%±3% for KN95, and from 97%±2% to 56%±4% for N95. The differences between two and three cycles were significant for both KN95 (p-value = 0.028±0.037) and N95 (p-value = 0.0009±0.0008). After UV sterilization, the filtration efficiency of KN95 for 250 nm – 500 nm particles was 94.4%±1.0% after two cycles, and 95.0%±0.6% after three cycles; and the filtration efficiency of N95 was 95.9%±1.4% after two cycles, and 96.9%±0.7% after three cycles. The differences were not statistically significant between two and three cycles for both KN95 (p-value = 0.754±0.187) and N95 (p-value = 0.448±0.267).
**Figure 1.** Effects of multi-cycle sterilization on filtration efficiency by aerosol size using H$_2$O$_2$ and UV treatment for (a) N95, and (b) KN9.

**Table 1.** Comparison of overall filtration efficiency and size specific (250 nm – 500 nm) filtration efficiency after multi-cycle H$_2$O$_2$ treatment.

| Mask Type   | H$_2$O$_2$ Treatment | Overall Filtration Efficiency | Size Specific Filtration Efficiency |
|-------------|----------------------|-------------------------------|-----------------------------------|
| Mask Type            | 2 Cycle Filtration Efficiency | 3 Cycle Filtration Efficiency |
|----------------------|-------------------------------|-----------------------------|
| KN95 – Civilian Antivirus Mask | 93%±3%                        | 84%±2%                      |
|                      | 90%±3%                        | 68%±3%                      |
| N95 – 3M 1860 Mask   | 98%±1%                        | 97%±2%                      |
|                      | 86%±5%                        | 56%±4%                      |

The size specific filtration efficiency is quite different from the overall filtration efficiency, especially after three cycle H₂O₂ treatment (see the Table 1). For instance, the overall filtration efficiencies for KN95 and N95 after three cycle H₂O₂ treatment are 90%±3% and 86%±5%, respectively; however, the size specific filtration efficiencies are only 68%±3% for KN95 and 56%±5% for N95, respectively.

Discussion

This study proposed that, in addition to considering the overall filtration efficiency, the filtration efficiencies for particle sizes similar to infectious particles should be considered. This study also found that the two different multi-cycle sterilization processes have unique effects on the filtration efficiencies by aerosol size of different masks. Multi-cycle sterilization with UV appears to have fewer negative effects than H₂O₂. Limitations include the small variety of mask manufacturers and the limited numbers of samples (n=5) for each mask and only two sterilization techniques evaluated. In addition, this study only evaluated the filtration efficiency after three sterilization cycles as this corresponds with guidance from
the American College of Surgeons for H₂O₂ sterilization. The filter material might degrade further with more cycles, which should be investigated for UV treatment.

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Figure/Table Legends

Figure 1. Effects of multi-cycle sterilization on filtration efficiency by aerosol size using H₂O₂ and UV treatment for (a) N95, and (b) KN95

Table 1. Comparison of overall filtration efficiency and size specific (250 nm – 500 nm) filtration efficiency after multi-cycle H₂O₂ treatment.