

Summary

This application note discusses N95 respirators, a widely used form of personal protective equipment in industry and healthcare applications. The respirator manufacturing process imparts unique material properties to the filtration media, improving the filtration efficacy but presenting challenges for disinfection and re-use.

Background

Amidst a global pandemic, the shortage of personal protective equipment (PPE) has been a pressing topic of discussion. The COVID-19 (SARS-CoV-2) infection rate has reached astounding levels, and healthcare facilities worldwide are overwhelmed with the influx of patients. Despite efforts to flatten the curve and reduce the number of concurrent active cases, there is an overwhelming strain on resources, including PPE. Healthcare facilities around the world are taking action to conserve PPE, with N95 respirators on the frontline of these discussions.



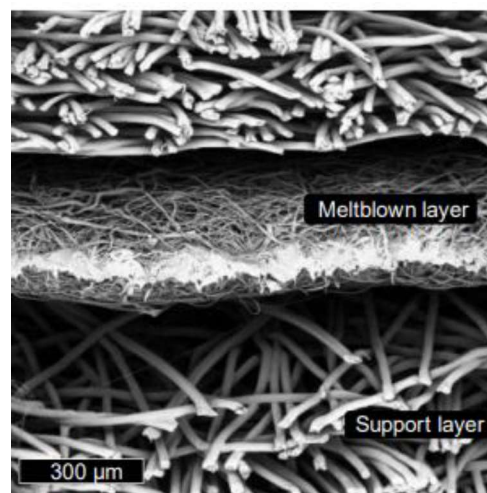
N95 respirators, commonly referred to as N95 masks, provide protection by filtering particulate material, thereby preventing the user from inhaling infectious media, such as viral aerosols. N95 respirators are distinguished from surgical masks in that they are tested and certified by the National Institute for Occupational Safety and Health (NIOSH) to meet a minimum filtration efficacy of 95 % for 0.3 μm NaCl aerosols [1]. This particle size is selected due to the challenge in filtering it; both larger and smaller particles are more readily filtered. Properly fitted N95 respirators provide a tight seal against the face, preventing leakage around the edges. Public awareness of PPE shortages has prompted a mass movement to make at-home versions of face masks. While these masks (as well as FDA-cleared surgical masks) provide some protection against large droplets and help contain the wearer's respiratory emissions, N95 respirators remain the gold standard for healthcare workers who are at heightened risk of infection. Unfortunately, suppliers of N95 respirators are unable

to meet the demand of the healthcare industry, and facilities have been forced to take action to conserve supply. Reports indicate hospitals are both limiting the number of N95 respirators distributed to each worker and relying on extended use or even re-use of the respirators, which are certified for single-use only [2]. In response to the supply shortage, the Center for Disease Control (CDC) relaxed guidelines for the re-use of respirators as well as permitted use of non-medical grade masks, such as respirators (similar to N95 certified) intended for industrial use [3] [4].

So what makes the N95 respirator stand apart from other filtration masks, and if these respirators are being re-used, what disinfection methods have shown the most promise in decontaminating while maintaining filtration efficacy?

Electrostatic Filtration

N95 respirators are comprised of multiple fibrous layers. A typical construct includes a spun-bond polypropylene outer layer, a middle melt-blown polypropylene filtration layer, and an inner spun-bond polypropylene layer, though additional layers and antiviral agents may be incorporated to inactivate viruses [5] [6] [7]. In general, spun-bond fibers can be used for filtration, with the primary mechanism of particulate filtration being mechanical entrapment. Spun-bond filtration efficacy, however, suffers from the relatively large fiber diameters (~10 – 50 μm) and correspondingly large pore sizes in these fiber beds. Improved filtration can be achieved by increasing the thickness or basis weight of the filter, but with the consequence of a larger pressure drop across the filter. For respiratory devices, a larger pressure drop translates to increased difficulty breathing. That is why the N95 respirators are more common for daily use than the more efficacious N99 or N100 respirators (with 99 and 99.97 % filtration efficacy, respectively). Thus, in the N95 respirator, the exposed spun-bond layers primarily serve to shape the mask and protect the interior filtration layer, rather than offering the primary means of particle filtration. That role is taken by the interior melt-blown layer.



Cross-section of N95 respirator; Figure 2B in [7].

The melt-blown filtration layer in N95 masks are generally composed of polypropylene. Polypropylene is a commodity grade plastic that is widely used in commercial products, such as packaging, textiles, and water bottle caps. In and of itself, polypropylene does not impart exceptional filtration efficacy. As with any polymer product, the manufacturing and processing conditions are as important to the product performance as the material itself. Melt-blowing is a fiber

drawing process that utilizes compressed air to eject thin streams of polymer melt at the tip of a nozzle. Under controlled conditions, the melt-blowing process produces uniform fibers on the order of 1 – 10 μm in diameter. The increased fiber surface area to volume ratio, alone, results in improved filtration efficacy relative to spun-bond fibers. However, the filter performance is further enhanced by the unique physicochemical properties of the fiber resulting from the melt-blowing and corona charging processes used in manufacture, resulting in polarization of the fibers.



Polarization is a spontaneous effect of melt-blowing due to the inherent processing conditions [8]. The polymer is heated sufficiently high to lower the viscosity of the melt, allowing for fiber formation. However, the high temperatures that are used, particularly for polypropylene, result in deliberate thermal degradation, oxidation, and the formation of free radicals within the polymer. Furthermore, the compressed air streams acting on the polymer melt result in high elongational forces. As such, the polymer chains are strained from the stretching flow, which decreases the energy barrier to bond rupture. Autoionization of the polymer can occur as a result of such thermofluctuational elongation of chemical bonds [8] [9] [10]. Due to rapid cooling of the fibers in the melt-blowing process, the resulting charges are stabilized, and the fibers are polarized, or placed in what is termed an electret state. The magnitude of the polarization is further amplified by entrapment of charge carriers transferred from the metallic spray nozzle [8] [9] [10]. Inherent defects in polymer structure, such as atomic groups with large dipole moments, act as structural traps that capture the ions transferred from the metal nozzle. The resulting electret state of the melt blown fibers enhances the filtration capability beyond simple mechanical capture of particles due to size restriction.

The charges contained within and at the surface of the fibers electrostatically attract and capture particles, improving filtration, particularly for small particles that are more difficult to capture mechanically. While the melt-blowing process inherently results in electrization of the fibers, the magnitude of the electret field in melt-blown filters is typically further augmented by corona charging. Corona discharge processing of polyolefins is a well-known technique to change the surface energy to improve adhesion, amongst other properties. A high voltage electrode in the vicinity of the melt-blown fibers ionizes air and injects charge into the fibers through field charging [11]. Studies have shown that the location of the corona discharge process affects the efficiency of charging [11] [12]. Specifically, corona charging in the melt state (near the spinneret) is not efficient, as the charges can migrate through the molten, mobile, and polymer. Once the fibers are solidified, the charges can be embedded and trapped within the fiber.

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The quality of a filter is characterized both by the ability of the filter to capture particulate and by the resulting pressure drop across the filter. Melt-blown fibers have relatively high porosity from the deposition process, thereby minimally restricting airflow through the filter (low pressure drop). Filters prepared by melt-blowing are able to achieve high filtration efficacy due to the improved filtration resulting from the electrostatic filtration mechanism. Corona charging has been shown to increase the filtration efficacy from 76 to 99.9 %, for example [12]. Hence, N95 respirators maintain their breathability but provide a strong barrier to inhalation of potentially harmful or infectious particulate.

Disinfection

While charge carriers in melt-blown polypropylene are captured in trapping centers characterized as “strong” due to the relatively low frequency of attempts to escape, there remains a tendency for charge to dissipate with time [8]. In filtration devices such as the N95 respirators, this decay means that there is a shelf life, or expiration date beyond which the filtration efficacy will decline. Amidst a shortage of N95 respirators, charge dissipation presents a challenge for re-use and disinfection.

The SARS-CoV-2 virus has been shown to remain viable on surfaces for up to 72 hours [13]. In order to safely re-use N95 respirators that have trapped viral aerosols, the viral load must be reduced prior to re-use. Common sterilizing or disinfection¹ techniques include irradiation methods (gamma, electron beam, UV-C irradiation), solution-based treatments (ethanol, chlorine-based solutions), gaseous treatments (ethylene oxide, vaporized hydrogen peroxide, steam), and thermal methods (dry heating). N95 respirators are approved only for single use, but amidst the ongoing crisis, the CDC and NIOSH acknowledged that disinfection methods may need to be considered to overcome the shortage in supply [13].

¹ N95 masks are not provided in a sterile form. Re-sterilization is therefore not necessary; it is adequate to disinfect (or decontaminate), reducing the viral and bacterial loads, but not completely eliminate them.

While there are certainly gaps in the understanding of how various disinfection methods affect the performance of N95 respirators, many studies have evaluated the effect of disinfection methods on filtration efficacy (of note, most studies have not evaluated the efficacy of the method specifically against the SARS-CoV-2 virus strain) [7] [14] [15] [16] [17] [18]. The CDC has identified vaporized hydrogen peroxide (VHP), ethylene oxide (EtO), and UV-C (also known as ultraviolet germicidal irradiation, UVGI) as the leading disinfection methods for consideration for re-use of N95 respirators [13]. Considering the electrostatic filtration mechanism utilized by N95 filters, the limitations of the other techniques can be understood.

The small molecules used in the solvents of solution-based disinfection methods can penetrate into the fibers, releasing entrapped charges [7]. As such, a loss of electrostatic attraction reduces the filtration efficacy. Some studies have identified a greater decline in performance for ethanol disinfection than for chlorine-based solutions (e.g. bleach) [7] [14]. This is likely due to the hydrophobicity of polypropylene, rendering it more resistant to penetration by water molecules. Therefore, the embedded charges are less affected by disinfection with aqueous solutions. Extended exposure duration and reoccurring disinfections, however, result in a gradual loss of filtration efficacy. Liao et al. reported a sharp drop in filtration efficacy only after five repeated steam sterilization cycles [7]. Autoclaving has further shown to deteriorate respirator performance by causing warping of the mask under the high temperature steam. Deformed respirators result in a loss of seal around the face, further reducing the ability to filter particulate.

Gamma and electron beam irradiation are effective sterilization methods that can penetrate through materials, allowing for products to be sterilized within packaging. For used N95 respirators, this would provide an advantage in that the mask could be stored in a sealed container after use, thereby limiting handling of the contaminated respirator. However, these methods have been shown to drastically reduce filtration efficacy [15]. The ionizing radiation is suspected to discharge the electret state of the melt-blown polypropylene resulting in a loss of electrostatic filtration. UVGI, while an ionizing radiation source, has reduced energy relative to gamma and electron beams. Therefore, UVGI is not as penetrating, which may result in less discharge of embedded charges in the bulk of the fiber. As a consequence of reduced penetration, UVGI suffers from shadowing effects, in which subsurface layers may not be thoroughly sterilized [13]. Studies have shown that the filtration efficacy is unaffected through ten UVGI disinfection cycles [7]. However, a decline in material strength has been reported, suggesting that the material degradation caused by the UV exposure may limit successive UVGI disinfection cycles [16].

EtO and VHP treatments are among the most promising and widely used methods for disinfection of N95 masks during the current pandemic. EtO has been shown not to affect the filtration efficacy or the airflow restriction of the N95 respirator [14]. However, EtO is a carcinogenic vapor. While the concern is mitigated by an extended aeration period following the disinfection, there may be hesitation to utilize un-validated EtO procedures. Therefore, VHP has been at the forefront of N95 disinfection processes. Through twenty consecutive VHP cycles, studies have shown that N95 respirators maintain filtration efficacy and experience no loss of fit or seal [17] [18]. Further, in the presence of air, hydrogen peroxide rapidly converts to oxygen and air, leaving no harmful residues on the respirator. In fact, the FDA authorized use of the Battelle Critical Care Decontamination System™, which utilizes VHP to disinfect compatible N95 respirators [13]. At the time of release of this report, eight mobile disinfection units had been distributed across the country, with the goal to provide free disinfection services up to \$400 million across 60 deployment sites [19].



Conclusions

The high filtration efficacy of N95 respirators is achieved due to the electret properties imparted during manufacture. Due to the added electrostatic filtration mechanism, N95 filters are able to remain highly porous while providing an effective barrier to inhalation of potentially harmful or infectious particulate. The relative instability of the electret state presents a challenge for re-use and disinfection of N95 respirators, since many common disinfection methods result in charge dissipation that compromises the filtration efficacy. However, VHP, EtO, and UVGI have shown promising results in disinfection, and mobile VHP decontamination units have been distributed across the country to disinfect N95 respirators for re-use.

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