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Do industrial N95 respirators meet the requirements to be used in healthcare? - A possible solution to respirator shortages during the next pandemic

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Abstract

Shortages of surgical N95 respirators (surgical N95 FFRs) can occur during a pandemic. To understand if industrial N95 FFRs have FDA required fluid penetration resistance and flammability, five NIOSH approved N95 models were evaluated using the ASTM F1862 method and flammability using the 16 CFR 1610 method, respectively. Three models passed both fluid penetration resistance and flammability indicating that some N95 models on the market can be used as surgical N95 FFRs during a pandemic.

Keywords

Fluid penetration resistance; Flammability; Biocompatibility

INTRODUCTION

National Institute for Occupational Safety and Health (NIOSH) approved N95 filtering facepiece respirators (N95 FFRs) are widely used in many occupational settings to reduce exposures to dusts and various particulate hazards. N95 respirators are certified by NIOSH using the 42 CFR Part 84 respirator approval process.[1] Surgical N95 FFRs (often called “Surgical N95 respirators”) are a special type of NIOSH approved N95 FFRs, which also have the additional requirements of fluid penetration resistance, flammability protection,[2] and biocompatibility.[3]

On May 17, 2018MOU FDA published a final order in the Federal Register to activate the November 2017 Memorandum of Understanding (MOU) between CDC/NIOSH and FDA

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DISCLAIMER

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to exempt a subset of N95s intended for use in healthcare from premarket notification requirements subject to conditions and limitations.[4] This exemption was intended to decrease the regulatory burden on some respirator manufacturers, and eliminate private costs and expenditures required to comply with certain regulations. The result of the FDA final order is a single review conducted under an expanded CDC/NIOSH respirator approval process that includes its and FDA's prior requirements, as well several new post market requirements. As a result of this activity, FDA no longer provides a clearance for the devices, and thus defers to the CDC/NIOSH approval (see exceptions in the MOU). This revised federal procedure retains the rigor as previously required under the FDA. Additional rigor has been put in place by CDC/NIOSH through its post market audit of these products. Post market audits provide data needed to determine if additional requirements should be incorporated in the CDC/NIOSH-approval process.[4] The 2017 MOU between FDA and CDC through NIOSH, provides a framework for coordination and collaboration on the regulation of surgical N95 respirators and N95 respirators.[4] The MOU states that NIOSH will continue to approve N95 FFRs as per 42 CFR Part 84, and in addition, will assess the fluid resistance, flammability,[2] and biocompatibility,[3] which have been part of FDA's premarket evaluation.

FDA classifies medical devices based on the risks associated with the device and by the device's safety and effectiveness. Surgical N95 FFRs not only provide protection against aerosols, like all FFRs, but they also provide additional protections against droplet sprays, such as respiratory secretions (eg, from a cough or a sneeze) and blood (eg, resulting from a surgical procedure). Surgical N95 respirators are not designed with an exhalation valve because exhaled air containing infectious particles may compromise the sterile field in a surgical setting. While Surgical N95 FFRs are the most widely used in healthcare[5], they only make up a small segment of the overall FFR market.[6]

The additional FDA requirements for surgical N95 FFRs involves assessing manufacturer supplied data for fluid resistance, flammability,[2] and bio-compatibility.[3] FDA recommends the evaluation of fluid penetration resistance using the ASTM F1862 method.[7] A synthetic blood is used to evaluate the penetration at 450, 550, and 635 cm/sec velocities. Absence of penetration at 450, 550, and 635 cm/sec velocity represents low, medium, and high resistance level of the respirator model, respectively.[7] FDA recommends flammability testing using the Consumer Product Safety Commission CS-191-53 flammability (16 CFR 1610) and other methods.[2] Flammability class 1 and class 2, representing normal flammability of fabrics accepted for use in clothing materials, are recommended for operating room use. Flammability class 3 materials are highly flammable, which are allowed in healthcare with a warning statement. Surgical N95 FFRs are also evaluated for bio-compatibility using the ISO-10993-1 standard.[3]

Surgical N95 respirators are used to reduce the inhalation of infectious aerosols from air and high-risk aerosol generating procedures in healthcare to prevent the spread of diseases such as the current COVID-19[8,9] Infected persons cough and sneeze and spread the disease through droplets containing viruses. The rate of surgical N95 FFRs used in healthcare increases substantially during respiratory infectious disease events (eg, pandemic), resulting in respirator shortages.[10] One possible solution to help mitigate a shortage is to expand the

supply of surgical N95 FFRs by including the larger pool of N95 FFRs used in industrial applications. These N95 FFRs are not routinely tested for fluid resistance and flammability, not marketed for hospital use, nor required to meet the additional surgical N95 respirator protections.

This study will evaluate, using data previously published,[6,11] as well as from this study for additional N95 FFRs to determine whether non-FDA cleared ("industrial use") N95 FFR models on the market would meet the fluid resistance and flammability requirements for FDA clearance as surgical N95 FFRs. Previous studies as well as this study did not collect data that can be used to inform the biocompatibility of N95 respirators.

MATERIALS AND METHODS

Respirators: Eleven N95 FFR models were evaluated for fluid resistance and flammability. Of the 11 N95 models selected for fluid resistance, 6 models were tested in the previous study.[6] Five additional N95 models were tested in this study. Table 1 shows the manufacturers and models. None of the devices had an exhalation valve. FDA cleared surgical N95 respirators do not have exhalation valves because exhaled breath of a patient that exits through exhalation valves could spread infectious microorganisms and contaminate the sterile field in the operating room.

Synthetic blood penetration resistance: Resistance to a synthetic blood penetration of respiratory devices was evaluated using the ASTM F1862 standard test method[7] as described previously.[6] The synthetic blood penetration test was conducted by only 1 test operator at the National Personal Protective Technology Laboratory of the NIOSH in Morgantown, WV. In this method, each respirator sample was equilibrated at 21°C and 85% relative humidity for 6 hours in an incubation chamber and then mounted on a synthetic blood penetration test apparatus. Synthetic blood (2 ml) was injected horizontally at 30 cm to the test respirator sample for durations of 0.825 seconds and 0.55 seconds corresponding target velocities of 450 cm/sec and 635 cm/sec, respectively. The synthetic blood penetration test is a visual pass/fail test. The absence of red color on the concave (inner) side of the respirator within a minute indicates the respirator is resistant to blood penetration and passed the blood penetration test.[7] In this study, 32 samples of each model were tested with a 2 ml synthetic blood at only 450 cm/sec (corresponding to human diastolic blood pressure) and at 635 cm/sec (corresponding to human systolic blood pressure) velocities. Twenty-nine or more samples should be resistant to synthetic blood penetration to pass the test. ASTM F1862 test is done at 450, 550, and 635 cm/sec velocities. None of the models were evaluated for penetration at 550 cm/ sec velocity.

Flammability: The flammability level of N95 FFRs was evaluated following the Consumer Product Safety Commission CS-191-53 flammability (16 CFR 1610) method[12,13] as described previously.[11] Five samples (each 5 × 15 cm) were cut from each respirator model. Each specimen was clamped in the sample holder and pre-conditioned in an oven at 105±3° C for 30 minutes. The specimen was removed from the oven, kept at room temperature, and supported on the specimen rack at a 45° angle. The position of the specimen was adjusted, so that the tip of the indicator finger just touched the surface of the specimen. The sample

was ignited as described previously[11] and the burn times for 5 samples of each model were obtained. The burn time represents the time elapsed from the time of ignition until the stop thread is severed. The average burn time for 5 specimens of each test device or fabric material was calculated.

The average burn times of >3, 3.5 to 7.0, and <3.0 seconds represent flammability class 1, class 2, and class 3, respectively. Biocompatibility was not assessed; however, the NIOSH regulation 30 CFR Part 11.61[14] requires that "respirator components which come into contact with the wearer's skin shall be made of nonirritating materials." This requirement has served America's workplace settings for about 50 years.

RESULTS AND DISCUSSION

Table 1 shows the combined synthetic blood penetration and flammability results for N95 FFRs. Seven out of 11 N95 models showed resistance to fluid penetration at 450 cm/sec velocity, of which, 5 models were also resistant at 635 cm/sec. Seven out of 11 N95 models passed the fluid penetration test at 450 cm/sec velocity, while 5 of which passed at 635 cm/sec. The 5 models that passed the penetration test at 635 cm/sec are considered as high-level resistance category. The other 2 models passed the test only at 450 cm/sec, indicating either low or medium level resistance, because penetration was not evaluated at 550 cm/sec. Passing the fluid penetration test at 450, 550 or 635 cm/sec velocity is a requirement for FDA clearance.[2] The ASTM test velocities correspond to the velocities of blood exiting a small arterial puncture during surgical procedures at human blood pressures of 10.7, 16.0, and 21.3 kPa (80, 120, and 160 mmHg, respectively). Outside the surgical setting, for routine patient care, these velocities also may simulate the velocities of virus-packed particles expelled from an infected person's mouth and nose during cough and sneeze. Overall, the results showed that 7 out of 11 N95 FFR models commonly available on the market passed the FDA requirement of resistance to fluid penetration.

Fluid resistance may be claimed if the device passes ASTM F1862 at any levels.[2] Surgical masks that show passing results at higher velocities are more fluid resistant.

The flammability results showed that none of the 11 models ignited, and therefore were assigned flammability class 1.[11] The relatively lower flammability level for respirators is not surprising because plain surface fabrics weighing >88.2 g/m^2, and olefin (eg, polyethylene and polypropylene) fibers used for FFR construction are exempted from flammability testing requirement.[12] Indeed, the weight of N95 FFR media tested was between 140–469 g/m^2,[11] which far exceeded the weight limit for flammability testing exemption. The results indicate that recent N95 FFRs on the market weighing >88.2 g/m^2 may not require flammability testing.

The construction of N95 FFRs using components containing no skin irritating materials is a requirement under 30 CFR Part 11.61.[14] Respirators are in use for a long time without any adverse skin effect indicating that manufacturers adhere to the use of biocompatible materials in respirators. Now, for the surgical N95 approval requirements, a biocompatibility requirement and testing is part of the MOU between FDA and CDC. Since the promulgation

of 30 CFR Part 11.61,[14] manufacturers continue to produce FFRs not sensitive to human skin which are expected to meet the biocompatibility requirement. Moreover, manufacturers supplied biocompatibility test results obtained for a group of subjects may not be applicable to workers in different workplace settings because of the difference in the immune response of individuals. Taken together, the results indicate that several non-FDA cleared N95 models on the market may meet the fluid resistance, flammability and possibly biocompatibility requirements for surgical N95 respirators.

The exemption of N95 FFRs and surgical N95 FFRs from 510(k) premarket notification is likely to decrease the regulatory burden on the industry and will reduce costs associated with surgical N95 FFR approval. The findings from this study, could lead some manufacturers to submit applications to NIOSH to consider the additional protections required by the FDA. Thus, the streamlined NIOSH approval process could increase the availability of surgical N95 respirators for healthcare use during pandemic if manufacturers typically not interested in the healthcare market, enter the market.

CONCLUSIONS

Seven out of 11 NIOSH approved N95 respirator models evaluated in the study showed resistance to synthetic blood penetration and flammability required for FDA clearance as surgical N95 respirators. The results showed several N95 FFR models on the market would pass FDA clearance for fluid resistance, flammability, and possibly biocompatibility suggesting that some models could be used to augment the nation’s supply of surgical N95 respirators during pandemic induced shortages.

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Table 1

Resistance to synthetic blood penetration and flammability for N95 filtering facepiece respirators (FFRs)

N95 FFRs (manufacturer and model)	Resistance to synthetic blood penetration		Flammability class
	Test velocity		
	450 (cm/sec)	635 (cm/sec)	
1. 3M (Model 9210) St Paul, MN	Pass	Pass	Class 1
2. Drager (Model 1350) Pittsburgh, PA	Pass	Pass	
3. Drager (Model 1750) Pittsburgh, PA *	Pass	Pass	
4. Kimberly-Clark (Model 62126) Dallas, TX	Pass	Pass	
5. Sperian-Willson (Model SAF-T-FIT) Franklin, PA	Pass	Pass	
6. Condor (Model 22EL78) Grand Rapids, MI *	Pass	Fail	
7. Kimberly-Clark (Model R10) Dallas, TX *	Pass	Fail	
8. 3M (Model V-Flex) St Paul, MN *	Fail	Fail	
9. 3M (Model 8210) St. Paul, MN	Fail	Fail	
10. Moldex (Model 2200) Culver City, CA	Fail	Fail	
11. Moldex (Model Air Wave 4201) Culver City, CA *	Fail	Fail	

NOTE: ‘Pass’ indicates 29 or more samples out of 32 samples were resistant to synthetic blood penetration (ASTM F1862) at specified velocities.

* Indicates models tested in this study.