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Resistance to synthetic blood penetration of National Institute for Occupational Safety and Health-approved N95 filtering facepiece respirators and surgical N95 respirators

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Fluid resistance
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Background: Surgical N95 filtering facepiece respirators (FFRs), certified by the National Institute for Occupational Safety and Health (NIOSH) as a respirator and cleared by the Food and Drug Administration (FDA) as a surgical mask, are often used to protect from the inhalation of infectious aerosols and from splashes/sprays of body fluids in health care facilities. A shortage of respirators can be expected during a pandemic. The availability of surgical N95 FFRs can potentially be increased by incorporating FDA clearance requirements in the NIOSH respirator approval process.

Methods: Fluid resistance of NIOSH-approved N95 FFRs, and FDA-cleared surgical N95 FFRs and surgical masks was tested using the ASTM F1862 method at 450 and 635 cm/sec velocities and compared with the results from a third-party independent laboratory. Blood penetration through different layers of filter media of masks were also analyzed visually.

Results: Four N95 FFR models showed no test failures at both velocities. The penetration results obtained in the NIOSH laboratory were comparable to those from the third-party independent laboratory. The number of respirator samples failing the test increased with increasing test velocity.

Conclusions: The results indicate that several NIOSH-approved N95 FFR models would likely pass FDA clearance requirements for resistance to synthetic blood penetration.

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Surgical mask (SM) or facemask refers to the Food and Drug Administration (FDA)-cleared surgical, laser, isolation, dental, and medical procedure masks with or without a face shield. A SM covers the user's nose and mouth and provides a physical barrier to splashes/sprays of large droplets of body fluids.¹ SMs are used by health care personnel during surgical and nonsurgical procedures to protect both the patient and the health care worker from splashes/sprays of blood or other body fluids.² FDA clears SMs based on manufacturer-submitted test data and proposed claims.³

Manufacturers submit the test results for particle filtration efficiency, bacterial filtration efficiency, fluid resistance, differential pressure, and flammability for FDA clearance.³

The use of respirators certified by the National Institute for Occupational Safety and Health (NIOSH), at least as protective as a N95 filtering facepiece respirator (N95 FFR), is recommended during care of patients with diseases such as tuberculosis and measles and during aerosol-generating procedures on patients with certain infectious diseases (eg, seasonal influenza, novel influenza A, and Ebola virus disease).⁴⁻⁷ NIOSH tests and certifies the performance of FFRs according to requirements outlined in the US Title 42 Code of Federal Regulations (CFR) Part 84.⁸ For N95 FFRs, the primary tests are filtration efficiency and airflow resistance.

The need for N95 FFRs with SM capabilities (eg, fluid resistance and flammability) was initially addressed, starting in 1996, by the FDA with the introduction of surgical N95 respirators. These are NIOSH-approved N95 FFRs that have been cleared by the FDA for fluid resistance and flammability. The surgical N95 FFRs offer the protection of both an N95 FFR and a SM. Because of these properties, surgical N95 FFRs are preferably used by health care personnel

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when protection from either fluids or aerosols, or both, may be needed. Currently, FDA clears only a small percentage of the total number of NIOSH-certified N95 FFR models under the Surgical N95 Respirators category. The use of surgical N95 FFRs in surgical and nonsurgical environments increases during outbreaks involving a known or suspected respiratory pathogen. For example, a scarcity of respirators during the spread of severe acute respiratory syndrome⁹ and influenza¹⁰ has been reported.

One possible option to increase the availability of surgical N95 FFRs for protection against inhalational hazards would be to expand NIOSH certification of N95 FFR models to include additional protection for fluid resistance and flammability. To better assess this option, NIOSH published a request for information in the *Federal Register* (Docket CDC-2014-0005) on the desirability of incorporating additional requirements and tests in the 42 CFR Part 84 respirator approval process to match the FDA clearance requirements for surgical N95 respirators.¹¹ NIOSH provided data in the docket showing that non-FDA cleared, NIOSH-approved respirators were routinely used in health care and that several models of these types of devices were included in the United States Strategic National Stockpile for use during public health emergencies such as a pandemic. NIOSH solicited data on the performance of non-FDA cleared, NIOSH-approved respirators for fluid resistance against splashes/sprays faced by health care workers. Comments to the docket¹¹ did not include data on the fluid resistance properties of non-FDA cleared N95 FFRs.

Manufacturers evaluate fluid resistance of SMs and surgical N95 FFRs according to the ASTM F1862 method.¹² This method is also being used to test the fluid resistance of respirators for research purposes.¹³ The fluid resistance test is a qualitative method based on visual inspection. Resistance to synthetic blood penetration is tested at 3 different velocities; 450, 550, and 635 cm/sec, corresponding to the range of human blood pressures 80, 120, and 160 mm Hg, respectively. FDA clearance³ of a surgical N95 FFR requires testing of 32 samples for each model. Of the 32 samples, >29 (>90.6%) must pass the ASTM F1862 fluid resistance test at any of the above 3 velocities. FDA clears surgical N95 FFRs at 3 levels of fluid resistance based on their performance at 3 different velocities. Fluid resistance at low, medium, and high levels refers to the device passing the test at 450, 550, and 635 cm/sec velocities, respectively. The level of fluid resistance is directly related to the test velocity.¹⁴ Some models may pass the testing only at 450 cm/sec, whereas others may also pass at 550 cm/sec or even at 635 cm/sec. The model that passes the test at the highest velocity would have higher level of resistance compared with other models that pass the test only at the lower velocities (450 and 550 cm/sec).

In this study, NIOSH-approved N95 FFRs commonly used in industrial workplaces were evaluated for fluid resistance. N95 FFRs from 6 manufacturers were tested for resistance to synthetic blood penetration using the ASTM F1862 standard method at NIOSH (Morgantown, WV) and the results were compared with those obtained from a third-party independent (TPI) laboratory (Nelson Laboratory, Salt Lake City, Utah). In parallel, resistance testing was done for 3 FDA-cleared surgical N95 FFR and 2 SM category devices. The pass/fail results of N95 FFRs, surgical N95 FFRs, and SMs at 450 and 635 cm/sec velocities were evaluated. The consistency of the test method was assessed by comparing the results obtained from NIOSH laboratory with the results from the TPI laboratory. The results, limitations of the test method, and future needs are discussed.

MATERIALS AND METHODS

Test materials

Six N95 FFR models, 3 surgical N95 FFR models, and 2 SM models were selected for this study. Two surgical N95 models were

chosen for their identical physical appearance with 2 non-FDA cleared N95 models, whereas others were selected randomly from leading manufacturers (based upon market share) and from those in the Strategic National Stockpile. The manufacturers and devices are: N95 FFRs: 3M (model 8210; St. Paul, MN), 3M (model 9210), Dräger (model 1350; Pittsburgh, PA), Moldex (model 2200; Culver City, CA), Kimberly-Clark (model 62,126; Dallas TX), and Sperian-Willson (model SAF-T-FIT; Franklin, PA); surgical N95 FFRs: 3M (model 1860), 3M (model 1870), and Kimberly-Clark (model 46,727); SMs: 3M (model 1820) and Precept (model 15,320; Arden, NC). The N95 FFRs were labeled randomly as A, B, C, D, E, and F, the surgical N95 FFRs as G, H, and I, and the SMs as J and K. None of the N95 FFRs and surgical N95 FFRs had an exhalation valve.

Test apparatus

A synthetic blood penetration test apparatus (Blood Spurt Tester, model SDL, Atlas LLC, Rock Hill, SC), similar to the 1 described in the ASTM standard,¹² was used in our study. The test apparatus consists of a specimen-holding fixture, a targeting plate, a pressurized fluid reservoir, a pneumatically actuated valve with an interchangeable canula (18-gauge stainless steel with an internal diameter of 0.084 cm), and a valve controller. The canula size was suitable to test synthetic blood penetration at arterial blood pressures ranging from 80-120 mm Hg corresponding to 450-635 cm/sec velocities. The specimen holder and the supporting frame of the fixture were rigid to resist the impact of the blood-spraying process. The height of the specimen holder was 420 mm, corresponding to the height of the synthetic blood reservoir. A targeting plate with a 0.5-cm hole was placed 1 cm in front of the mask to ensure that the synthetic blood hit the target area of the mask. The actuated valve was attached to a stable metal stand to withstand any flex during activation by the pneumatic control. The valve was positioned according to the ASTM F1862 method so that the exit of the canula was 30.5 cm from the point of impact on the specimen mask.

Preparation of test apparatus and calibration

The fluid reservoir was filled with approximately 1 L fresh synthetic blood (Johnson, Moen & Co Inc, Rochester, Minn) and a canula was installed on the front of the pneumatically controlled valve. The canula used in the method is a 1.27-cm (0.5-in) long 18-gauge stainless needle with an internal diameter of 0.084 cm (0.033 in). The synthetic blood penetration test was performed only at velocities of 450 and 635 cm/sec, corresponding to blood pressures of 80 and 160 mm Hg, respectively. The reservoir pressure was adjusted to approximately 8 psi or 12 psi to achieve a velocity of 450 cm/sec or 635 cm/sec, respectively. The test apparatus was calibrated for each target velocity by delivering the synthetic blood for a 1-second difference in spurt duration. The weight of synthetic blood delivered for a 0.5 second and a 1.5 second spurt were collected in separate small beakers. The 2 weights of the samples were recorded and the difference between the 2 weights was calculated. According to ASTM F1862, the target difference in weight plus lower and upper limits for a velocity range should be within 2% of the target. The target difference in weights for the test at the target velocities of 450 and 635 cm/sec were 2.506 g and 3.537 g, respectively. In this study, the acceptable weight range was between 2.456 g and 2.556 g for the 450 cm/sec velocity and was between 3.466 g and 3.607 g for the 635 cm/sec velocity, which were within the specified ranges.

During testing, 2.0 mL (2.0 g) synthetic blood was directed to the test sample for durations of 0.825 seconds and 0.550 seconds corresponding to target velocities of 450 cm/sec and 635 cm/sec,

Table 1

Synthetic blood penetration for N95 filtering facepiece respirator (N95 FFR), surgical N95 respirator (Surgical N95 FFR), and surgical mask (SM) models*

Type	Model	Synthetic blood penetration					
		450 cm/sec			635 cm/sec		
		Total	Pass	Fail	Total	Pass	Fail
N95 FFR	A	14	13	1	15	11	4
N95 FFR	B	15	15	0	15	15	0
N95 FFR	C	15	15	0	15	15	0
N95 FFR	D	15	10	5	15	14	1
N95 FFR	E	10	10	0	10	10	0
N95 FFR	F	10	10	0	10	10	0
Surgical N95 FFR	G	14	14	0	15	13	2
Surgical N95 FFR	H	14	14	0	15	15	0
Surgical N95 FFR	I	15	15	0	15	15	0
SM	J	15	14	1	15	14	1
SM	K	10	10	0	10	7	3

*Test was done at the National Institute for Occupational Safety and Health laboratory (Morgantown, WV).

respectively. After every 15 samples, a check was performed to ensure that the test apparatus was still delivering 2.0 g synthetic blood by collecting and weighing the output passing through the targeting hole. When the blood sample delivered showed a shift of >0.10 g, all prior data since the last calibration were discarded. The canula was also cleaned after testing 15 samples.

Before use, test samples were conditioned in an environmental chamber (Caron Environmental Chamber, model 6001-1, Marietta, Ohio) for 4-6 hours at a temperature of 21°C ± 5°C and 85% ± 5% relative humidity, to simulate the temperature and humidity conditions of the mask on a wearer. Each test sample was removed from the environmental chamber and was mounted on the testing apparatus, centered, and 2-mL synthetic blood was dispersed at the target velocity within a minute. The synthetic blood penetration through the sample was assessed visually. A control mask for each model for all category devices was used for comparison. A drop of the blood was placed on the inner side of the control mask and compared with the color on the inner side of the test sample.

DATA ANALYSIS

The fluid resistance pass/fail data for each test velocity at the NIOSH laboratory and TPI laboratory were combined for statistical analysis. The data at the 2 different test velocities and the 2 laboratories were compared by Wilcoxon signed-rank test matched pairs using SPSS software (version 20, IBM-SPSS Inc, Armonk, NY).

RESULTS AND DISCUSSION

Table 1 shows only NIOSH test results for synthetic blood penetration for N95 FFRs, surgical N95 FFRs, and SMs. All samples of four N95 FFR models showed no synthetic blood penetration at both 450 and 635 cm/sec test velocities. One of the other 2 N95 FFR models (ie, A) had penetration for one of 14 samples at 450 cm/sec and 4 of 15 samples at 635 cm/sec. Unexpectedly, model D showed blood penetration for 5 of 15 samples at 450 cm/sec and only 1 of 15 samples at 635 cm/sec. The reason for the higher number of penetrations at the lower velocity is not clear. In the case of the surgical N95 FFR category, all samples from 2 models (ie, H and I) passed the test at both velocities. All samples of model G passed the test at 450 cm/sec, but showed penetration for 2 samples at the higher velocity. Of the 2 SM models tested in the study, model J showed penetration for 1 of 15 samples at both 450 and 635 cm/sec. The other model (ie, K) showed penetration for 3 of 10 samples at 635 cm/sec, but none at 450 cm/sec.

Table 2

Comparison of blood penetration results from National Institute for Occupational Safety and Health (NIOSH) and the third-party independent (TPI) laboratory at 450 and 635 cm/sec velocities

Type	Model	Percentage of samples passing the test			
		450 cm/sec		635 cm/sec	
		NIOSH	TPI	NIOSH	TPI
N95 FFR	A	93	90	73	70
N95 FFR	B	100	100	100	100
N95 FFR	C	100	100	100	100
N95 FFR	D	67	100	93	20
N95 FFR	E	100	100	100	100
N95 FFR	F	100	100	100	100
Surgical N95 FFR	G	100	100	92	100
Surgical N95 FFR	H	100	100	100	100
Surgical N95 FFR	I	100	90	92	80
SM	J	93	100	93	100
SM	K	100	90	70	60

N95 FFR, N95 filtering facepiece respirator; SM, surgical mask; Surgical N95 FFR, surgical N95 respirator.

The synthetic blood penetration results obtained at the NIOSH laboratory were compared with the results obtained by the TPI laboratory (Table 2). The number of samples tested at each velocity at the NIOSH laboratory varied from 10-15 for each model, whereas, only 10 samples per model were tested at TPI laboratory. Despite the difference in the number of samples tested at the 2 laboratories, the penetration results obtained at NIOSH were comparable to those from the TPI laboratory. For example, the same 4 N95 FFR models (ie, B, C, E, and F) that showed no penetration at the NIOSH laboratory also had no penetration at TPI laboratory. Model A showed penetration for some samples at the 2 test velocities in both laboratories. Similarly, some samples of model D showed penetration at 635 cm/sec at both testing laboratories. No penetration was obtained for 1 surgical N95 FFR model (ie, H) at both 450 and 635 cm/sec in both testing laboratories. In the case of SMs, 1 model showed penetration at both velocities at the NIOSH laboratory, but, no penetration at TPI laboratory. The other model had penetration only at 635 cm/sec at the NIOSH laboratory, but at both velocities at the TPI laboratory. Overall, 11 of 22 test results were the same between the 2 laboratories. Although the NIOSH laboratory found more samples (ie, 7) with higher failure rates than the TPI laboratory (ie, 4), the difference was not statistically significant ($P = .327$).

For FDA clearance, synthetic blood penetration for 32 samples of each device is evaluated using the ASTM F1862 standard test method to achieve an acceptable quality limit of 4% as defined in the American National Standards Institute/American Society of Quality Control¹⁵ standard. An acceptable quality limit of 4% includes minor deviations from the standard, such as the acceptance of synthetic blood penetration for <3 samples (<9.4%). To pass the test, <3 samples can show penetration at 450 cm/sec (the lowest of the 3 test velocities) at a minimum. A device that passes the test only at 450 cm/sec indicates its lower fluid resistance level. A very high fluid resistant device passes the penetration test at all 3 velocities.

Table 3 shows the blood penetration results for the total number of samples for all models tested in the study. The results for the NIOSH and TPI laboratory samples were combined, because only a limited number of samples were tested at each laboratory. Moreover, a similar trend in penetration was obtained between the 2 laboratories. Samples from 4 out of 6 models of NIOSH-approved N95 FFRs showed no penetration. Of the other 2 N95 FFR models, model A had penetration for 2 of 24 samples at 450 cm/sec and 7 of 25 samples at 635 cm/sec, indicating that model A may pass the resistance test at 450 cm/sec, but not at 635 cm/sec. Model D

Table 3

Synthetic blood penetration for N95 filtering facepiece respirators (N95 FFRs), surgical N95 respirators (surgical N95 FFRs), and surgical masks (SMs). Combined test results from the National Institute for Occupational Safety and Health laboratory and the third-party independent laboratory at 450 and 635 cm/sec velocities

Type	Model	450 cm/sec				635 cm/sec			
		Total	Pass	Fail	% Pass	Total	Pass	Fail	% Pass
N95 FFR	A	24	22	2	92	25	18	7	72
N95 FFR	B	25	25	0	100	25	25	0	100
N95 FFR	C	25	25	0	100	25	25	0	100
N95 FFR	D	25	20	5	80	25	16	9	64
N95 FFR	E	20	20	0	100	20	20	0	100
N95 FFR	F	20	20	0	100	20	20	0	100
Surgical N95 FFR	G	24	24	0	100	25	23	2	92
Surgical N95 FFR	H	24	24	0	100	25	25	0	100
Surgical N95 FFR	I	25	24	1	96	25	23	2	92
SM	J	25	24	1	96	25	24	1	96
SM	K	20	19	1	95	20	13	7	65

showed penetration for several samples at the lower velocity at 1 of the laboratories (see Table 2), but not at the other. Because of the contradictory results obtained at the lowest velocity, whether model D will meet the fluid resistance requirement is uncertain. Three surgical N95 FFR models were tested in the study, of which only model H had no failures at either velocity. All samples of model G passed the test at 450 cm/sec, whereas model I had 1 sample that failed the test at 450 cm/sec. Two SM models were tested and only 1 of 20 samples of both models failed at the lowest velocity. For this initial study, we did not test the full recommended sample size of 32, so it is not possible to say with 100% certainty whether the N95 FFR models with <3 failures would meet the FDA clearance requirements or not. However, because four of the models had no failures even at the highest velocity for the first 20–25 samples, it would seem likely that they would pass if testing had continued to the recommended sample size.

Surgical N95 FFR models H and I were specifically included in this study because they appear to be identical to 2 non-FDA cleared N95 FFRs models (ie, C and E). Models C and I are both flat-folding respirators from the same manufacturer and visually appear to be identical except for color (1 is orange and the other is white). Similarly, E and H are identical in appearance, except for the labeling and packaging. As shown in Table 3, both pairs exhibited similar fluid resistance properties.

Overall, the results showed an increase in synthetic blood penetration with increasing test velocity (Fig 1), similar to other studies.¹⁶ For comparison between the 2 velocities, the pass/fail data obtained in the 2 test laboratories were combined.

The number of samples of the 3 categories of masks that showed penetration increased with increasing velocity from 450–635 cm/sec. N95 FFR, surgical N95, and SM masks showed penetration for 7, 1, and 2 samples at 450 cm/sec, which increased to 16, 4, and 8 samples at 635 cm/sec. The percentage of samples that showed penetration was significantly ($P = .043$) higher at 635 cm/sec than at 450 cm/sec. Penetration for large numbers of samples at higher velocity can be expected because an increase in the test velocity is likely to increase the permeability of the masks for fluids, including synthetic blood. Other factors include the configuration of the different types of filter media used in the multilayer construction of the mask. In general, the hydrophobic filter media-containing models are less likely to show penetration because of their ability to retard the penetration of a hydrophilic challenging test agent. The presence of a hydrophobic filter media on the outer surface may provide a barrier to the entry of hydrophilic water-based synthetic blood.¹⁷ The lack of penetration of the devices may be maintained when the outer surface is hydrophobic and dry. Penetration can be expected when the outer layer is wet.

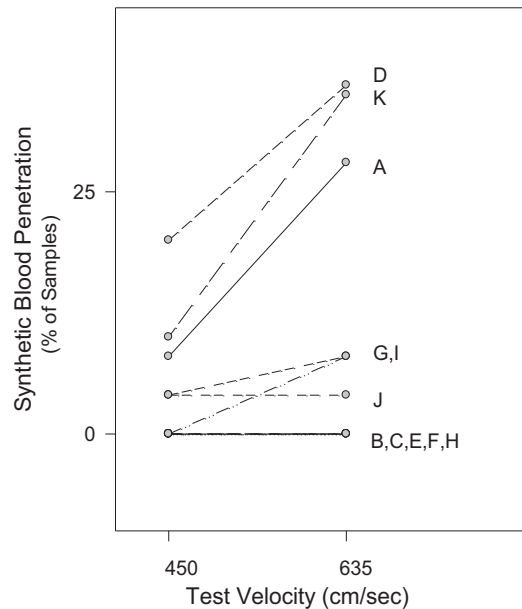
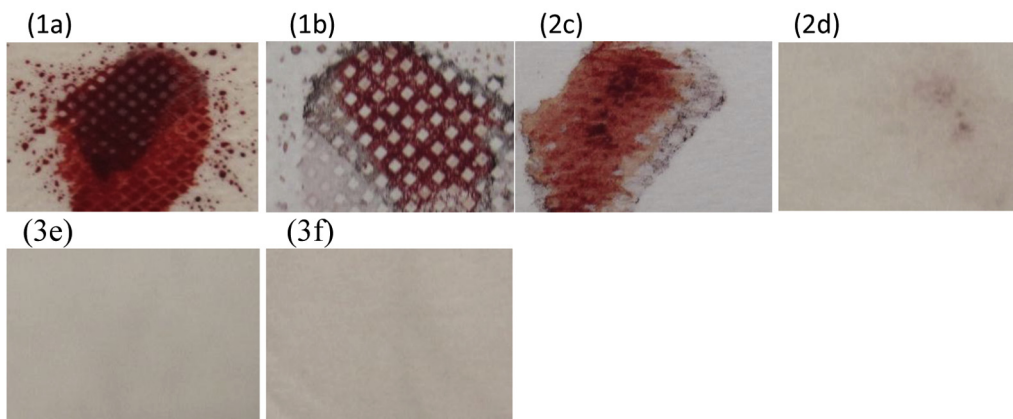


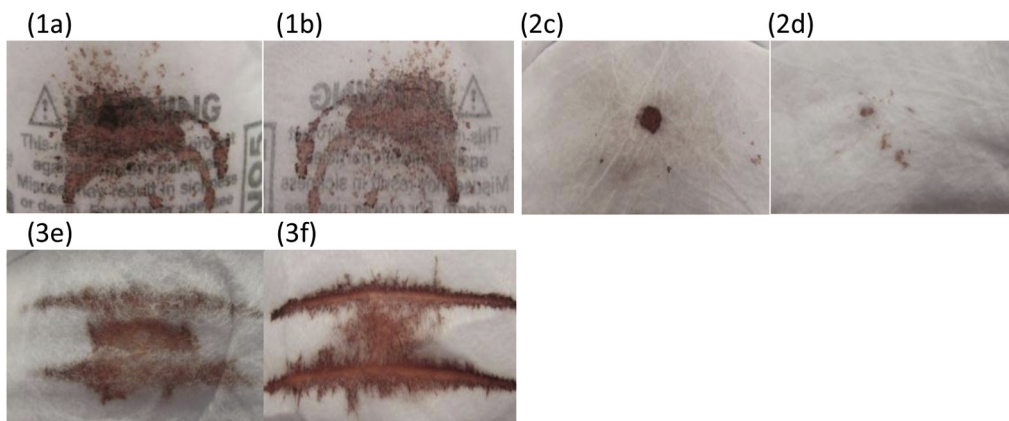
Fig 1. Effect of test velocity on the synthetic blood penetration for 6 N95 filtering facepiece respirators (A, B, C, D, E, and F), 3 surgical N95 filters (G, H, and I) and 2 surgical masks (J and K). Penetration was tested at 450 cm/sec and 635 cm/sec velocities for all samples of different models at both National Institute for Occupational Safety and Health and the third-party independent laboratories.

To gain more information on synthetic blood resistance of the mask, penetration through the different layers of the masks were analyzed visually. All of the models block the initial spray, but differences were found in how the synthetic blood moved through the layers of the device. Figure 2 shows the blood penetration through different layers of respirator models. A representative N95 FFR sample of model C, 1 of the 4 N95 models that passed the resistance testing, was analyzed for blood penetration through the different layers. Blood color was seen on the outer and inner sides of the outer layer (model C, 1a and 1b, respectively) and middle layer (model C, 2c and 2d, respectively). There was no red color on the outer or inner side (model C, 3e and 3f, respectively) of the innermost layer of the mask demonstrating no blood penetration. Two N95 FFR models (A and D) failed the test as shown by the blood color on the inner side of the masks. Model A had 3 layers of filter media. The outer and inner side (model A, 1a and 1b) of the outermost layer showed a wide area of the synthetic blood color. The middle layer had a relatively smaller area with color on the outer surface (model A, 2c), which diminished on the inner side (model A, 2d), indicating very little blood penetration. Surprisingly, a larger area of blood color was seen on the outer surface of the innermost layer (model A, 3e and 3f), which increased along the crease line on the inner side (model A, 3f) exposed to the face. The result was consistent between the different samples of the same model. The results are supported by the design of the respirator with different layers of filter media. The outer layer was thin and hydrophobic and blood was able to penetrate at the velocities tested in the study. The dense middle hydrophobic layer can be separated into 2 layers, but is considered as a single layer for simplicity. Although the hydrophobic middle layer appears to decrease blood penetration dramatically as shown by the reduction in the area of blood color, it actually allowed the blood to pass through it. This can be seen by the appearance of a wide area of blood color on the innermost hydrophilic layer, because of its affinity toward the water-based synthetic blood. In the case of model

Model C



Model A



Model D

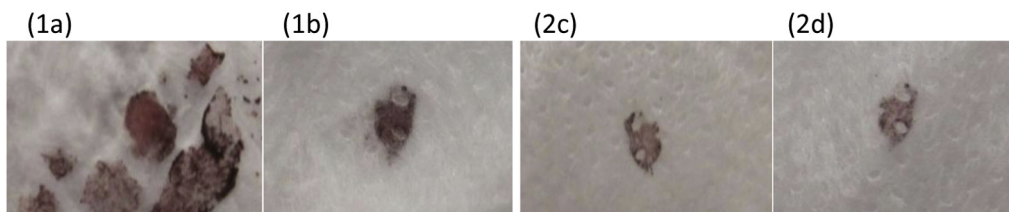


Fig 2. Synthetic blood penetration through different layers of N95 filtering facepiece respirator (N95 FFR) models C, A, and D. The outside and inside (a and b, c and d, and e and f, respectively) of the outer (1), middle (2), and inner (3) layers of the N95 FFR models. Model C represents 1 of the models that passed the penetration test. Model D had only 2 layers.

D, there was an outer shell and 2 hydrophobic layers with a second shell layer in between (Fig 2, bottom panel). The 2 hydrophobic layers were not sufficient to prevent blood penetration at the test velocities. The results indicate that the numbers of hydrophilic and hydrophobic filter media, packing density of the layers, and the arrangement of the layers on the outer or inner side of the mask may influence blood penetration.

The penetration of synthetic blood through hydrophobic filter media layers raises a question on the interpretation of the test method. In the case of model A, the inner side of the middle hydrophobic layer showed only traces of blood color. However, blood penetration through the middle layer could be seen by the wide area of color on the outer and inner sides of the innermost hydrophilic layer. This indicates that the innermost layer should be made of a hydrophilic material to reveal penetration of synthetic blood. In the absence of a hydrophilic layer, the device may still allow blood penetration, but it may not be easily identified by the

test method. The results indicate the need for the development of a more accurate test method that can identify blood penetration on the inner side of the mask with either a hydrophilic or hydrophobic layer.

The synthetic blood penetration test addresses the potential for infectious biologic fluids reaching/touching the human face in a surgical environment. There are scenarios in which splashes/sprays occur outside of surgical procedures. For example, significant volumes of respiratory secretions from infected individuals are released at high velocity in the form of a sneeze or cough, which can spray or splash on a nearby individual wearing an SM or FFR. The possibility that some devices may allow the penetration of biologic fluids exists because of the wide variation in their construction. The design of many surgical N95 FFRs and N95 FFRs prevents the inner surface of the respirators from touching a user's face. On the other hand, some models with a flat-fold type respirator may touch the facial skin during breathing, indicating that

nasal secretions can diffuse through the mask under high humidity conditions of the mask. One study tested human subjects wearing SMs to evaluate the physiologic, thermal, and subjective influence of an SM on the wearer.¹⁸ Those authors¹⁸ reported that 11% of subjects complained about the SM sticking to the face during inhalation. Further studies are needed to understand the diffusion of biologic fluids through filter media in SMs, surgical N95 respirators, and FFRs.

The results for synthetic blood penetration tests obtained in our study may have implications for respirator use in the health care environment. FDA clears only a small percentage of NIOSH-approved N95 FFRs as surgical N95 respirators. The extensive use of surgical N95 FFRs in surgical and nonsurgical health care practices results in shortages during emergencies and pandemic events involving a respiratory pathogen. To address this issue, NIOSH could incorporate additional test requirements in 42 CFR Part 84 respirator approval process to parallel the protections in the FDA clearance of surgical N95 respirators. Current FDA clearance procedures³ accept NIOSH respirator certification in lieu of filter efficiency performance and differential pressure. In theory, similar arrangements for streamlined approvals could be made if NIOSH began evaluating fluid resistance as part of its certification process. Our study showed 4 out of 6 N95 FFR models approved by NIOSH but not cleared by FDA likely also meet the fluid resistance requirement for surgical N95 FFR clearance. Even the 2 N95 FFR models that demonstrated lesser fluid resistance ability still had pass rates of 80% and 92% at the lowest velocity, insufficient to meet requirements of the standard, but suggestive of ability to provide some level of fluid resistance. A detailed analysis of the pros and cons of NIOSH incorporating fluid resistance requirements into 42 CFR Part 84 respirator approval and its influence on infection control policies and respirator shortages is outside of the scope of this article, but is needed.

The ability of all of the N95 FFRs tested to pass 80% or greater at the lowest velocity also presents an opportunity to scrutinize the need for this specific test in determining suitability of respirators for use in medical environments. For situations with increased respirator use like a pandemic, the need for protection against projectile blood at 435 cm/sec may be less common than the need for protection against lower-velocity splashes/sprays from coughing, sneezing, and talking. Additional studies are needed to determine whether non-FDA cleared N95 FFRs would be sufficient for these types of situations, but the preliminary data here are promising.

Limitations of this study include that only 6 non-FDA cleared NIOSH-approved N95 FFR models were tested for synthetic blood penetration. Additional models need to be tested to provide conclusive information on whether most N95 FFR models would meet existing FDA requirements for penetration resistance of synthetic blood. The ASTM F1862 standard test method requires 32 samples per model to obtain an acceptable quality limit of 4%. This means that 29 or more samples should pass the test. In our study, only 10-15 samples per model in each laboratory were tested for synthetic blood penetration. Future studies should use the 32 samples per model described in the ASTM F1862 standard test method. Other limitations include the subjective nature of the blood penetration test as well as the variation in the test results obtained by different test performers in the same laboratory as well as between laboratories.

Nevertheless, the synthetic blood penetration results obtained in the study indicate that many NIOSH-approved N95 FFRs may meet the FDA clearance requirement for synthetic blood penetration. Although many models would likely pass the synthetic blood penetration criterion, whether they would pass the flammability tests for FDA clearance remains to be evaluated. Studies on the blood penetration for longer times may provide information on any

change in the penetration pattern, when the exposed mask is worn for a protracted period.

CONCLUSIONS

Four out of 6 NIOSH-approved N95 FFR models that were not cleared by FDA that were tested in our study showed resistance to synthetic blood penetration at 450 and 635 cm/sec velocities. Similar results were obtained from a TPI laboratory. The combined results for resistance to blood penetration from the 2 laboratories indicate that these models may pass the FDA clearance process provided they also pass the flammability requirement. As expected, the numbers of respirator samples that failed the test increased with increasing test velocity. Respirator design, using different numbers of both hydrophilic and hydrophobic filter media layers at different packing densities, may influence resistance to blood penetration.

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