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Effects of volume, velocity, and composition on the resistance to synthetic blood penetration of N95 filtering facepiece respirators and other head/facial personal protective equipment

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Abstract

Surgical N95 filtering facepiece respirators (surgical N95 FFRs) are National Institute for Occupational Safety and Health-approved N95 filtering facepiece respirators (N95 FFRs) cleared by the Food and Drug Administration for resistance to liquid penetration and flammability. A recent study showed that several N95 FFR models performed as well as surgical N95 FFRs in synthetic blood penetration tests that evaluate resistance to penetration by horizontal projection. This aspect, in addition to the influence of other factors on liquid penetration, are not well studied. To address this issue, the effect of liquid volume (1 mL and 2 mL), spray velocity (450 cm/sec and 635 cm/sec), and liquid composition (synthetic blood and diluted synthetic blood) were evaluated. Four types of common protective devices were studied: N95 FFRs, surgical N95 FFRs, surgical masks, and powered air-purifying respirator (PAPR) hoods. For each protective device type, five models were analyzed using a protocol based on the F1862 ASTM International (2017) test method. Reduced liquid volume had a significant effect in only 3 of 20 models. Increased velocity had significantly greater penetration in 9 of 20 models. Diluted synthetic blood had significantly more penetration in 8 of 20 models. This last result was not expected because, in hydrostatic tests, surface tension of the diluted blood would be expected to reduce penetrability; however, across all models tested, data showed that the diluted spray was more penetrable. The study results suggest that fluid composition may be as important as velocity when considering liquid spray penetration. Furthermore, the penetrability of a spray may be inversely related to the penetrability through direct hydrostatic contact.

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Disclaimers and disclosures

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Keywords

F1862; FFR; liquid penetration; PAPR; surgical respirator

Introduction

Healthcare personnel may be exposed to potentially infectious blood and bodily fluids, especially during medical procedures. In the past, surgical masks and surgical N95 filtering facepiece respirators (surgical N95 FFRs) used in healthcare have been regulated by the Food and Drug Administration (FDA) under: Surgical Apparel (1988). The FDA requires 510(k) premarket notification for class II medical devices unless they are exempt according to the Food and Drug Administration Regulatory Modernization Act of 1997 by the 105th U.S. Congress (1997) and the 21st Century Cures act by the 114th United States Congress (2016). To evaluate surgical masks or surgical N95 FFRs for resistance to synthetic blood penetration, the FDA has recognized the ASTM F1862 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity). While the FDA approves surgical apparel, the National Institute for Occupational Safety and Health (NIOSH) is responsible for the certification of respirators under: Approval of Respiratory Protective Devices (1995). Prior to 2018, a surgical N95 FFR was approved by NIOSH and cleared by the FDA. To help streamline the process for evaluations of filtering facepiece respirators (FFRs) used in healthcare settings, the FDA and NIOSH developed a Memorandum of Understanding that is recorded with by Food and Drug Administration (2017). Subsequently, the FDA published its final order in May 2018, and now evaluates respirators under the streamlined FDA/NIOSH process for Medical Devices in “Exemption from Premarket Notification: Class II Devices; and Surgical Apparel” (Medical Devices; Exemption From Premarket Notification 2018, 22846–22848). These changes have resulted in an interest in establishing a better understanding of the ASTM F1862 test method.

The ASTM F1862 test ejects 2 mL of synthetic blood through a cannula to the external surface of a mask. Resistance to penetration may be observed visually by the absence of synthetic blood on the interior surface of the mask. Tests are conducted by ejecting synthetic blood at 3 different velocities (450, 550, and 635 cm/sec) to correspond to a small arterial puncture at human blood pressures of 10.7, 16.0, and 21.3 kPa.

Rengasamy et al. (2015) evaluated N95 FFRs, surgical N95 FFRs, and surgical masks using the ASTM F1862 Standard Test Method. Samples from each model contained fewer than 32 replicates (i.e., $n < 32$). At high velocities (635 cm/sec), 5 of 11 models passed all tests. Four of these models were N95 FFRs and one model was a surgical N95 FFR. Of the two surgical masks evaluated, one performed well (>90%) while the other had several failures. Spray velocity is not the only factor that affects liquid penetration. ASTM F1862 specifies a single volume (2 mL) of synthetic blood, which may not adequately represent an occupational exposure to a smaller spurt of 1 mL that a phlebotomist might typically experience during a venipuncture procedure. Additionally, the choice of a single liquid type (synthetic blood) may not adequately represent an irrigated water/blood mix typical for a

medical task or dental procedure. Diluted synthetic blood may be less penetrable than the undiluted suspension because liquids under hydrostatic pressure with low surface tension have greater penetration through protective fabrics, as described by Unsal et al. (2005).

To better understand the potential of ASTM F1862, this study evaluated five unique models from each PPE type: N95 FFRs, surgical N95 FFRs, surgical masks, and powered air-purifying respirator (PAPR) hoods. The overall objective was to evaluate common types of PPE for liquid spray penetration against factors that would be typical in an occupational setting.

Methods

Four types of PPE were tested: N95 FFRs, surgical N95 FFRs, surgical masks, and PAPR hoods. For each type of PPE, five models were selected.

A synthetic blood penetration test apparatus similar to the device described in ASTM F1862 was used (Blood Spurt Tester, model SDL, Atlas LLC, Rock Hill, SC). The test apparatus consisted of a specimen-holding fixture that holds the specimen being tested, a targeting plate, an interchangeable cannula, a valve controller that activates the spray, and a pressurized liquid reservoir (Figure 1). The cannula size was selected to test synthetic blood penetration at arterial blood pressures ranging from 10.7–23.3 kPa 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 valve controller was attached to a stable metal stand to withstand any flex during activation. The valve was positioned so that the exit of the cannula was 30.5 cm from the point of impact on the specimen mask.

Synthetic blood specified in ASTM F1862 was obtained from the distributor (Johnson Moen & Co, Rochester, MN) and was stored in ambient laboratory conditions. Tests were conducted as described in Test Method F1862, however the volume tests were conducted with reduced liquid (1 mL), the velocity tests were omitted for the moderate velocity condition (550 cm/sec), and the composition tests used synthetic blood diluted with deionized water at 1:3 ratio to raise surface tension. The surface tension was measured using a du Noüy Precision Tensiometer (Model 70535, CSC Scientific Company, Inc., Fairfax, VA) as specified by ASTM International (2014) after 20 min in an undisturbed petri dish as described in Portnoff et al. (2019). The surface tension tested at a 20-min equilibrium time was 58.0 dynes/cm for diluted synthetic blood and 42.4 dynes/cm for undiluted synthetic blood. Viscosity was measured using a DV1 viscometer (AMETEK Brookfield, Middleboro, MA). Viscosity was 3.5 cP for diluted synthetic blood and 8 cP for the undiluted synthetic blood.

The following conditions were tested: 2 mL of synthetic blood at 450 cm/sec, 1 mL of synthetic blood at 450 cm/sec, 2 mL of synthetic blood at 635 cm/sec, and 2 mL of diluted synthetic blood at 450 cm/sec. The PPE was purchased from commercial vendors, and

each model was from the same lot. From each model, 128 specimens (4 conditions × 32 replicates) were randomly selected using a random number generator.

The presence of a hydrophobic filter media on the outer surface may provide a barrier to the entry of hydrophilic water-based synthetic blood, as described in Institute of Medicine (2008). Table 1 shows hydrophobicity for each N95 FFR and surgical N95 FFR model. The number of hydrophilic and hydrophobic filter media layers and their location in the front, middle, or inside of the mask vary among different models.

Test procedure

Prior to testing, specimens were conditioned in an environmental chamber (Caron Environmental Chamber, Model 6001-1, Marietta, OH) for 4–6 hr at 21 ± 5° C and 85 ± 5% RH, as specified in ASTM F1862. The liquid reservoir was filled with synthetic blood and a clean cannula was installed. Calibrations were performed by delivering the synthetic blood for a 0.5 sec and a 1.5 sec spurt. Volumes were collected in separate small beakers. The difference between the two weights was calculated. The reservoir pressure was adjusted until the difference in weight was within ±2%. Within 1 min of removal from the conditioning chamber, each specimen was mounted on the semicircular specimen holder. After exposure to a synthetic blood spurt, penetration through specimen was assessed visually. The absence of blood color on the inner surface of the mask was considered passing the test.

After fewer than 16 tests, before the cannula was cleaned, a check was performed to ensure that the test apparatus was delivering the correct volume of synthetic blood. When the blood sample weight deviated more than 2%, the calibration procedure was repeated. The test apparatus was calibrated specifically for each synthetic blood volume, velocity, and composition.

Pass criteria

Consistent with ASTM F1862, specimens were visually inspected after exposure. Synthetic blood on the interior of the mask was considered a “fail,” whereas a clean appearance on the inside of the mask was considered a “pass.” ASTM F1862 suggests a minimum of 32 specimens at each velocity to achieve an “acceptable quality limit” (AQL) of 4%. The AQL of 4% provides a tolerance for minor anomalies and finds <4 failures per 32 specimens to be acceptable. In other words, for a sample (n = 32) to “pass” the penetration test, not more than three specimens can fail. The FDA further classifies low, medium, and high fluid resistance levels to samples passing 450, 550, and 635 cm/sec, respectively. A two-proportion z-test was used to find significant differences between PPE models. Significance was determined for $p < 0.05$ with a 2-tail test.

Results

Significant differences were found with every factor that was evaluated. Some protective devices and certain models were more affected than others. Results are summarized in Table 2.

Effect of volume

The effect of volume was tested at 450 cm/sec using 2 mL and 1 mL of synthetic blood. Three of the five N95 FFR models were resistant (AQL <4%) with 2 mL were also resistant with 1 mL. In the case of the surgical N95 FFRs, all five models passed with both volumes. Four of five surgical mask models were resistant to penetration at 2 mL. One mask resistant with 2 mL was not resistant with 1 mL. This contradiction, being resistant to a high volume but not resistant to a lower volume, may be a statistical anomaly. All five PAPR hood models resisted liquid penetration at both volumes.

Effect of velocity

The effect of velocity was tested using 2 mL of synthetic blood at 450 and 635 cm/sec velocities. Three of the five N95 FFR models were resistant (AQL <4%) at 450 cm/sec, and one was at 635 cm/sec velocity. In the case of surgical N95 FFRs, all five models passed at 450 cm/sec and three models at 635 cm/sec. Four of five surgical mask models were resistant to penetration at 450 cm/sec, but only one model at the higher velocity. All five PAPR hood models resisted liquid penetration at 450 cm/sec; four models at 635 cm/sec.

Fewer models of the above category devices passing the liquid resistance at 635 cm/sec compared to at 450 cm/sec shows that increasing velocity increases penetration (i.e. decreases resistance to penetration). The decrease in resistance to penetration with increasing velocity is consistent with the results obtained by Rengasamy et al. (2017).

Effect of composition

The effect of composition was tested by comparing 2 mL of synthetic blood with 2 mL diluted (1:3) synthetic blood at 450 cm/sec. Three of five N95 FFR models were resistant with undiluted solution, whereas two of five were resistant with diluted solution. Of the five surgical N95 FFR models resistant to undiluted synthetic blood, three were resistant with the diluted solution. Four of five surgical mask models that were resistant to penetration did not resist penetration with diluted synthetic blood. All five PAPR hood models were resistant to both undiluted and diluted synthetic blood.

Because of the elevated surface tension, the diluted synthetic blood was expected to be less penetrable than the undiluted synthetic blood, however, in all statistically significant samples, the opposite occurred. Blood spurts may not follow the same norms as hydrostatic or mechanical penetration. Perhaps elevated surface tension could increase droplet cohesion of the fluid spray and therefore increase inertial energy that would cause increased penetration.

Three out of five NIOSH-approved N95 FFR models tested in the study showed resistance to synthetic blood penetration at 450 cm/sec, similar to FDA-cleared surgical N95 FFRs. Manufacturers may also be motivated to submit their products for a single approval process for the protection requirements of both NIOSH approval and FDA clearance in accordance with the FDA and NIOSH memorandum of understanding.

The synthetic blood penetration results for surgical N95 FFRs confirm the results that would be expected for FDA cleared surgical N95 FFRs. One surgical N95 FFR was susceptible to

penetration when the liquid composition was diluted. All PAPR hood models were resistant to liquid penetration and met the FDA requirement of liquid resistance.

Discussion

The reduced volume of 1 mL was not significantly different from the 2 mL spray volume for any of the surgical N95 FFR or PAPR models. One N95 FFR model performed significantly better with reduced volume. One surgical mask performed significantly better, yet another performed significantly worse with reduced volume. This may be attributed to variability in the product or the testing methods. In total, reduced volume had an effect in only three of the 20 models of PPE tested. This may indicate that much of the penetration in the test occurs with the first 1 mL of liquid.

Increased velocity (635 cm/sec) was significantly different in four of the five models of N95 FFRs and surgical masks. Increased velocity was significantly different in some of the surgical N95 FFR and PAPR models, however most models performed well at both low and high velocities. The ASTM F1862 test accounts for low and high velocities and our test results show that this is an important factor to include in a performance test.

Composition (1:3 dilution) was significantly more penetrable in all the surgical masks, in two of the N95 FFRs, and in one surgical N95 FFR. Fluid composition is not part of the ASTM F1862 test method, however composition did affect the results in 8 of 20 models. This suggests that the type of liquid splash or spray is an important factor to consider when evaluating barrier performance of PPE. Contrary to what we expected and what is known about direct contact hydrostatic penetration testing, the composition with low surface tension was more penetrable than the composition with high surface tension. One possible explanation is that the high surface tension contributes to a more cohesive spray and larger droplets. In any case, one should not assume that a change in composition will affect spray penetration and hydrostatic penetration in the same way, and may in fact have an inverse relationship.

When considering the ASTM F1862 test method, it is important to consider additional factors that may affect liquid penetration. Also, respirators and surgical masks that provide a wide range of resistance to liquid spray penetration do not cover eyes and head, a proper face shield should be worn for this protection. All PAPR models performed well under all conditions tested in this study and may provide relevant protection from liquid spray. Additionally, some N95 FFR models on the market appear to pass the ASTM F1862 synthetic blood penetration test. Manufacturers of these products may consider applying for surgical N95 FFR approval.

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References

105th U.S. Congress. 1997. H.R.1411: Food and Drug Administration Regulatory Modernization Act of 1997. Library of Congress.

114th United States Congress. 2016. H.R. 34: 21st Century Cures Act. Library of Congress.

Approval of Respiratory Protective Devices. 1995. 42 C.F.R.Part. 84.

ASTM International. 2014. Standard test method for surface and interfacial tension of solutions of paints, solvents, solutions of surface-active agents, and related materials. (ASTM D1331–14 A). West Conshohocken (PA): ASTM International.

ASTM International. 2017. Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity). (ASTM F1862/F1862M-17). West Conshohocken (PA): ASTM International.

Food and Drug Administration. 2018. Medical devices; exemption from premarket notification: Class II devices. HHS. 82 Fed Regist. 56763. Surgical Apparel; p. 22846–22848.

Food and Drug Administration. 2017. Memorandum of Understanding Between the Food & Drug Administration/Center for Devices & Radiological Health and the Centers For Disease Control & Prevention/National Institute for Occupational Safety & Health/National Personal Protective Technology Laboratory. (MOU 225-18-006).

Institute of Medicine. 2008. Preparing for an Influenza pandemic: personal protective equipment for healthcare workers. Washington (DC): The National Academies Press.

Medical Devices; Exemption From Premarket Notification. 2018. Class II devices; Surgical Apparel. 21 C.F.R. Sect. 878. 83; p. 22846–22848.

Portnoff L, Jaques PA, Furlong JL. 2019. The surface tension of synthetic blood used for ASTM F1670 penetration tests. J Test Eval. 47(2):20170285. doi:10.1520/JTE20170285

Rengasamy S, Sbarra D, Nwoko J, Shaffer R. 2015. Resistance to synthetic blood penetration of National Institute for Occupational Safety and Health-approved N95 filtering facepiece respirators and surgical N95 respirators. Am J Infect Control. 43(11):1190–1196. doi:10.1016/j.ajic.2015.06.014 [PubMed: 26231551]

Rengasamy S, Shaffer R, Williams B, Smit S. 2017. A comparison of facemask and respirator filtration test methods. J Occup Environ Hyg. 14(2):92–103. doi:10.1080/15459624.2016.1225157 [PubMed: 27540979]

Surgical Apparel. 1988. 21 C.F.R Sect. 878.4040.

Unsal E, Dane JH, Schwartz P. 2005. Effect of liquid characteristics on the wetting, capillary migration, and retention properties of fibrous polymer networks. J Appl Polym Sci. 97(1):282–292. doi:10.1002/app.21716

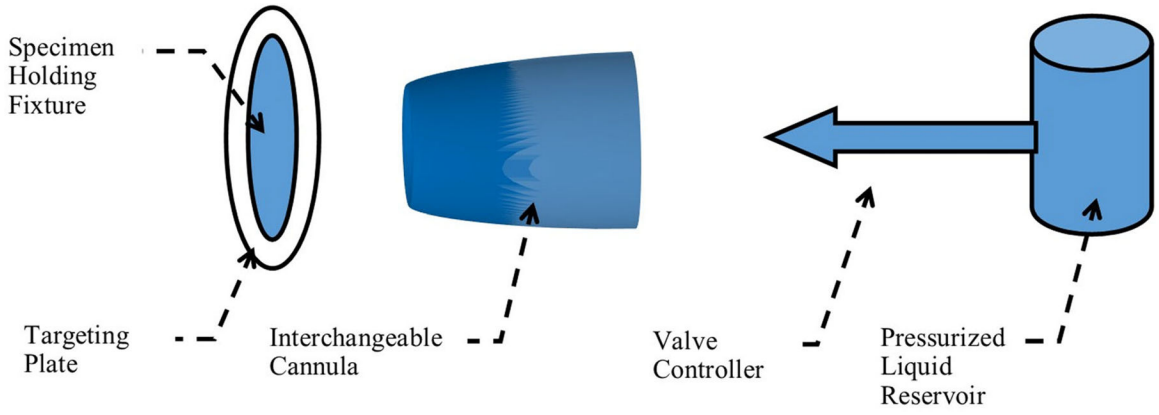

Figure 1.
Schematic of blood spurt test apparatus.

Table 1.

Hydrophilicity and hydrophobicity of inside and outside layers of respirators.

Mask, Manufacturer, Model	Outside	Inside
N95 FFRs		
Condor, 22EL78	+	+
Moldex Airware (4201)	−	−
Jackson Safety R-10	+	+
3M V-Flex (9105)	−	−
Dräger X-plore (1750)	−	−
Surgical N95 FFRs		
Sperian, HC-NB295F	−	−
Sperian, HC-NB095	+	−
AlphaProTech, Critical Cover 695	−	−
Moldex, 1512	−	−
Gerson, 1730	+	+

Hydrophilic (+) and Hydrophobic (−)

Hydrophilic and hydrophobic properties of filter material were evaluated by cutting two swatches measuring 3×3 cm^2 from each respirator model. Filter media layers from each FFR were physically separated with forceps. A 10 μL droplet of water was placed on each filter media layer and visually examined for 5 min.

Table 2.

Synthetic blood (SB) penetration through tested products (number passing/32 replicates); lot passing criteria is >90% based on an AQL of 4%.

Model	Condition 1 SB 2 mL 450 cm/sec	Condition 2 SB 1 mL 450 cm/sec	Condition 3 SB 2 mL 635 cm/sec	Condition 4 Diluted (1:3) 2 mL 450 cm/sec
N95 FFRs				
Condor (22EL78)	94%	100%	66%**	69%***
Moldex Airware (4201)	38%	88%*	6%**	13%***
Jackson Safety (R10)	91%	94%	53%**	94%
3M V-Flex (9105)	75%	63%	0%**	69%
Dräger X-plore (1750)	100%	100%	100%	100%
Surgical N95 FFRs				
Sperian (HC-NB2956F)	100%	100%	97%	100%
Sperian (14110446)	100%	100%	100%	100%
AlphProTech Crit Cover (695)	100%	97%	88%**	63%***
Moldex (1512)	100%	100%	100%	100%
Gerson (1730)	97%	97%	84%	84%
Surgical Masks				
Keystone (1826EL)	78%	100%*	34%**	38%***
Condor (4MKY1C)	94%	100%	63%**	53%***
Swift (3PAD7)	100%	100%	91%	84%***
Cellucap (1826)	97%	81%*	44%**	13%***
Precept (15320)	100%	94%	88%**	84%***
PAPR Hoods				
MSA (OptimAir)	97%	97%	100%	94%
3 M (Versaflow)	100%	100%	91%	97%
3 M (BE-10-3)	94%	100%	100%	100%
Dover (Sentinel XL)	94%	100%	88%	91%
Bullard (Tychem QC)	100%	100%	97%	97%

Statistically significant at $p < 0.05$ with 2-tail, two proportion z-test (R prop.test, ver. 3.6.1, R Foundation for Statistical Computing, Vienna, Austria).

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*Condition 1 vs. Condition 2

**Condition 1 vs. Condition 3

***Condition 1 vs. Condition 4