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ABSTRACT

The objective of this study was to investigate the protection level offered by a Powered Air-Purifying Respirator (PAPR) equipped with an improperly sized or stretched-out loose-fitting facepiece using constant and cyclic flow conditions. Improperly sized PAPR facepieces of two models as well as a stretched-out facepiece were tested. These facepieces were examined in two versions: with and without exhaust holes. Loose-fitting facepieces (size "large") were donned on a small manikin headform and challenged with sodium chloride (NaCl) aerosol particles in an exposure chamber. Four cyclic flows with mean inspiratory flows (MIFs) of 30, 55, 85, and 135 L/min were applied using an electromechanical Breathing Recording and Simulation System (BRSS). The manikin Fit Factor (mFF) was determined as the ratio of aerosol concentrations outside (C_{out}) to inside (C_{in}) of the facepiece, measured with a P-Trak condensation particle counter (CPC). Results showed that the mFF decreased exponentially with increasing MIF. The mFF values of the stretched-out facepiece were significantly lower than those obtained for the undamaged ones. Facepiece type and MIF were found to significantly affect the performance of the loose-fitting PAPR. The effect of the exhaust holes was less pronounced and depended on the facepiece type. It was concluded that an improperly sized facepiece might potentially offer relatively low protection (mFF < 250) at high to strenuous workloads. The testing was also performed at a constant inhalation flow to explore the mechanism of the particle-facepiece interaction. Results obtained with cyclic flow pattern were consistent with the data generated when testing the loose-fitting PAPR under constant flow conditions. The time-weighted average values of mFF calculated from the measurements conducted under the constant flow regime were capable of predicting the protection under cyclic flow regime. The findings suggest that program administrators need to equip employees with properly sized facepieces and remove stretched-out ones from workplace. Manufacturers should emphasize the importance of proper sizing with their user instructions.

Introduction

The Powered Air-Purifying Respirators (PAPRs) certified by the National Institute for Occupational Safety and Health (NIOSH) are used in a variety of occupational environments to reduce worker's exposure to gaseous and/or particulate contaminants. To receive approval from NIOSH, PAPRs must meet the certification requirements of 42 CFR 84.[1] However, NIOSH does not indicate how to choose an appropriately sized PAPR facepiece for an individual. In addition, user instructions do not always address "sizing" of facepieces when more than one size is available. Prior to this study, the implications of using an improperly sized PAPR facepiece have not been evaluated.

The Occupational Safety and Health Administration (OSHA) has published and enforces assigned protection factor (APF) for respiratory protective equipment. The APFs for PAPRs vary from 25–1,000 depending on the type of facepiece selected (half mask, full facepiece, helmet/hood, or loose-fitting facepiece).[2] While having the loose-fitting facepiece has the lowest APF of 25, this facepiece has several advantages compared to tight-fitting negative pressure air-purifying respirators: they require no fit testing, feature no breathing resistance, provide

cooling, and may be worn by workers with corrective eyewear.[3,4] These advantages are preferred by the healthcare workers (HCWs) according to the survey conducted by Baig et al.[5].

In a loose-fitting PAPR system, the ambient air supplied to the wearer is powered by a battery-operated fan. When the wearer's level of exertion is mild, the PAPR is intended to supply air flow which is measurably greater than the inhalation flow, thus establishing a positive pressure inside the facepiece during the majority of the breathing cycle. As the level of exertion increases, the breathing rate increases as well resulting in a greater minute volume. Consequently, the pressure inside the facepiece could become negative near the peak of each inhalation cycle, thus allowing the contaminated air to enter into the facepiece. This "over-breathing" could compromise the performance of a loose-fitting PAPR.[6] The problem may be more pronounced if the facepiece is improperly sized to the worker's head, which increases the size of the gap between the worker's face and the facepiece. Field experience has shown that some companies tend to order a single size facepiece (typically large), instead of purchasing an appropriately sized facepiece for each individual. This practice may simplify ordering and inventory, but it does not recognize the need to choose a properly sized PAPR facepiece for an individual when different sizes are available.

Numerous studies have been conducted on the performance of the NIOSH-certified N95 filtering facepiece respirators (FFRs)[7–11] and elastomeric half-masks.[12,13] However, only a few investigations have addressed the protection offered by the PAPRs. For example, Cohen et al.[14] obtained simulated workplace protection factors (SWPFs) for five PAPR models representing different brands and facepiece styles. These respirators were tested on 12 volunteers performing 12 exercises to simulate real workplace activities. The SWPF range for the loose-fitting hooded PAPRs was 240 to > 250,000, suggesting a high degree of protection as well as a large variance among the SWPFs. However, none of the investigations involving PAPRs intentionally tested improperly sized loose-fitting facepieces or explored the potential effect of a damaged (stretched-out) facepiece on PAPR performance. A damaged facepiece is a reality in some workplace settings given that this type of respirator may be used/re-used over a long time, often shared among employees, and may not be routinely removed from service when inspection programs are less than optimal.

The purpose of this investigation was to evaluate the protection level of improperly sized loose-fitting PAPR facepieces by using a manikin with cyclic breathing. Flows were selected to represent breathing at moderate, medium-to-high, high and strenuous workloads. Similar tests using constant flows were conducted to further investigate the mechanism of the particle penetration into the tested facepiece. This study was designed to evaluate the following factors: facepiece type, breathing flow rate and the role of facepiece exhaust holes on the performance of improperly sized loose-fitting PAPRs. A stretched-out facepiece was also investigated to provide quantitative information that may be of value for respirator program administrators.

Materials and methods

Powered air-purifying respirator (PAPR) with loose-fitting facepiece

A commonly used PAPR (EVA, Bullard Company, KY, USA) certified by NIOSH was selected for testing in this study. Selection was based on availability. One of the authors was responsible for training workers on proper use, including positioning of the facepiece and assistance with size selection, since more than one size was available. It contains a blower unit which draws air through a High-Efficiency Particulate Air (HEPA) filter and delivers the purified air into the facepiece. Among the two flow rates, 198 and 240 L/min, offered by the blower, the lower one was used in this study to produce a conservative situation whereby inhalation flow could feasibly exceed the blower flow. The lower blower flow rate provides a longer duration of operation and produces less noise. Consequently, users often find the lower blower flow advantageous. For comparison, NIOSH requires at least 6 ft³/min (170 L/min) during field use and this lower blower flow exceeds this requirement. Two versions of loose-fitting facepieces, 20LFL (Facepiece A, size "large") and 20LF2L (Facepiece B, size "large") of the same brand (Bullard Company, Cynthiana, KY) were used in this study. Facepiece B was designed for a narrow face. A stretched-out 20LFL facepiece (Facepiece C, size "large") was also evaluated in this study to simulate a "damaged" facepiece in a workplace. It was created by donning the facepiece onto an oversized manikin headform until the facepiece became stretched out and lost elasticity. It should be noted that we have observed respirators in the field with even greater levels of damage than the one used in this study. Figure 1 demonstrates that Facepiece C features a larger gap between the face and the facepiece compared to the other two facepieces (A and B).

The tested respirators are designed with exhaust holes (approximately 6 mm diameter) located near the chin area on the loose-fitting facepiece. These holes make the facepiece more comfortable to wear, help to keep the facepiece
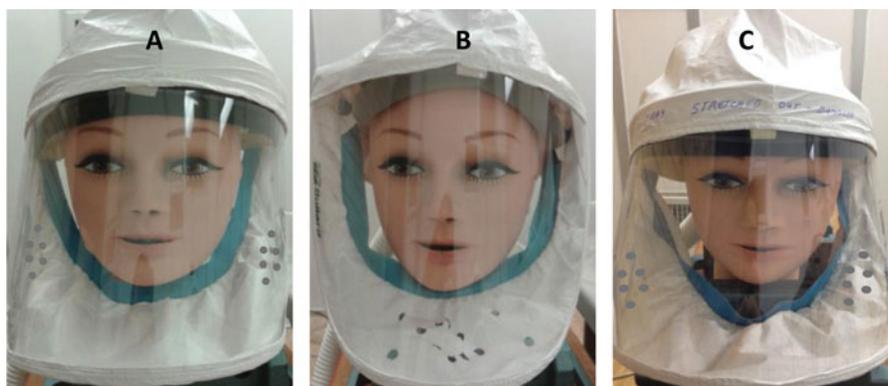
Figure 1. Tested loose-fitting facepieces (A: 20LFL; B: 20LF2L; C: stretched-out 20LFL).

from coming off the face, and reduce air flow noise. However, the "openings" may serve as a penetration pathway for particles to enter the facepiece. In order to evaluate the effect of the exhaust holes, additional tests were conducted with Facepieces A, B, and C using duct tape to cover the holes on both sides of the facepiece. The number of the exhaust holes was 12 (6 on the left side and 6 on the right side) for Facepieces A and C, and 14 (all in the middle) for the Facepiece B.

Experimental design and conditions

The experimental setup is presented in Figure 2. The tests were performed in an exposure chamber (volume $= 3.6 \times 2.4 \times 2.6$ m^3). As shown in Figure 2, the tested facepiece was donned on a manikin headform. The facial dimensions of the manikin fell into Cell 2 (considered as a small face) of the NIOSH Bivariate Panel.[15] The mouth and nostrils on the headform were open for inhalation and exhalation, to more closely mimic human breathing flow patterns. The breathing was performed using the electromechanical Breathing Recording and Simulation System (BRSS; Koken Ltd., Tokyo, Japan), which generated a sinusoidal flow pattern.[16] A 1-in diameter copper pipe was mounted and extended to the mouth and nostrils of the manikin to allow the movement of air in and out of the BRSS. Four cyclic flows with mean inspiratory flow (MIF) rates of 30, 55, 85, and 135 L/min were applied. All had the same breathing frequency of 25 breaths/min. The above-specified MIFs were established to represent breathing at moderate, medium-to-high, high, and strenuous workloads.[12] A HEPA filter was placed between the manikin headform and the BRSS to keep particles from re-entering the facepiece during exhalation so that the concentration measured inside the facepiece reflected solely the aerosol penetrated from the ambient environment and no particle inside the facepiece has an opportunity to be counted more than once. One sampling probe was installed to measure the aerosol concentration inside

the facepiece (C_{in}), and the other was placed 24 cm away from the inside probe to measure the outside concentration (C_{out}). Both probes were connected to a switching valve, which could be switched to sample the aerosol either inside or outside of the facepiece. The challenge aerosol was generated with a particle generator (Model 8026, TSI Inc., MN, USA) from a suspension containing 2 g of NaCl and 100 g of sterile, Millipore-filtered water. The generator was operated for 30 min before the testing to allow the challenge aerosol to reach a temporal homogenous concentration (within $\pm$ 10%). The total aerosol concentration was measured with a P-Trak condensation particle counter (Model 8525, TSI Inc., Shoreview, MN) operating in a size range of 20–1,000 nm. The fit factor determined on the manikin headform (manikin Fit Factor, mFF) was calculated as C_{out}/C_{in}. The experimental conditions are summarized in Table 1.

Cyclic and constant flow regimes

To further investigate the mechanism of the particle penetration into the tested facepiece, similar tests were conducted using constant inhalation flows. The flow rate (Q) ranged from 20–240 L/min with an increment of 20 L/min. The same experimental variables, including the facepiece type and exhaust holes condition, were applied under constant flow regime. The results of aerosol measurements conducted at the above-indicated constant inhalation flow rates (20, 40, 60, … L/min) were subjected

Table 1. Summary of the experimental conditions.

Variable	Levels
Facepiece type	A, B, C
Exhaust holes condition	covered; uncovered
MIF	30, 55, 85, 135 L/min[a]
Replicates	3
Total runs	$3 \times 2 \times 4 \times 3 = 72$

[a] The cyclic flows of MIF = 30, 55, 85, and 135 L/min (PIF = 47.1, 86.4, 133.5, and 212.0 L/min, respectively) were applied at breathing rate of 25 breaths/min.
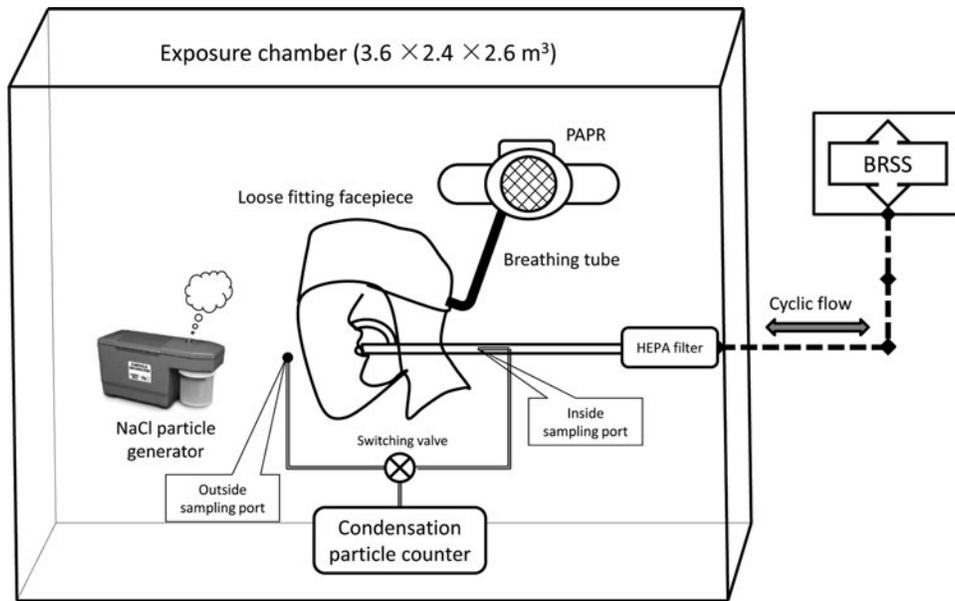
Figure 2. Experimental setup modified from He et al.[12] (BRSS = Breathing Recording and Simulation System; PAPR = Powered Air-Purifying Respirator.)

to a linear regression approximation, to determine a rate-specific mFF for any Q between 20 and 240 L/min. The rate-specific mFF values were converted to penetration (= 1/mFF); the penetration values were then integrated as a function of time and time-weighted following a sinusoidal breathing pattern

$$Q = Q_{PIF} \times \sin{(2\pi t/T)} \qquad (1)$$

Here, Q_{PIF} is the peak inspiratory flow (PIF) rate, which is a direct function of the MIF, T is the period of

the breathing cycle [at 25 breaths/min, T = (1/25 min)(60 s/min) = 2.4 s], and t is the time in seconds. This allowed us to calculate an integrated penetration and subsequently an integrated mFF for a cyclic flow regime corresponding to a specific Q_{PIF} and Q_{MIF}. Further, each calculated mFF value was compared to the corresponding experimental result (obtained at the same MIF under cyclic flow conditions). Figure 3 schematically shows the flow rate as a function of time at MIF = 135 L/min and breathing frequency of 25 breaths/min (an example). It is seen that non-filtered air can enter a facepiece only during half of
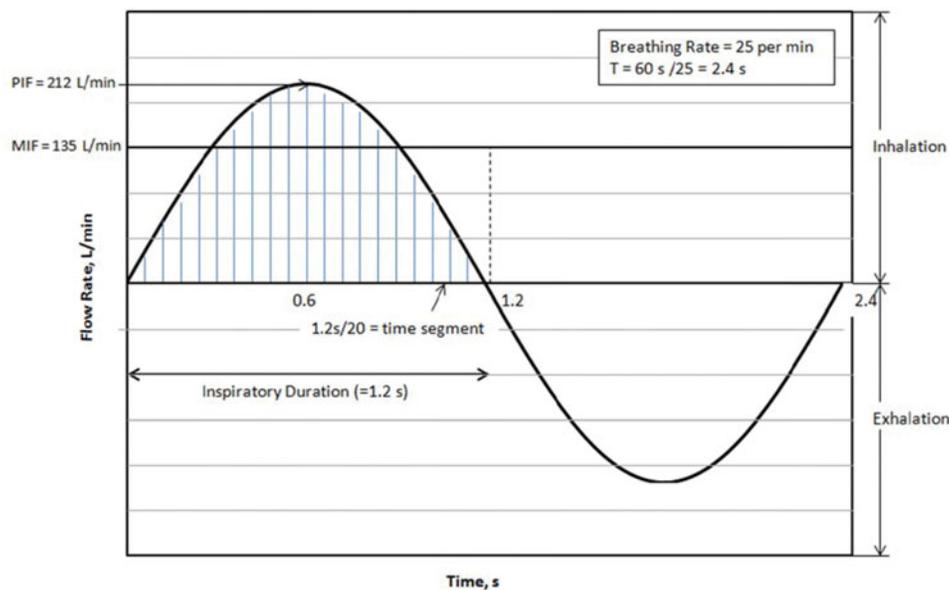

Figure 3. Flow rate as a function of time at PIF = 212 L/min (MIF = 135 L/min) and breathing frequency of 25 breath/min (schematics for numerical integration). The schematics is modified from Haruta et al.[16]
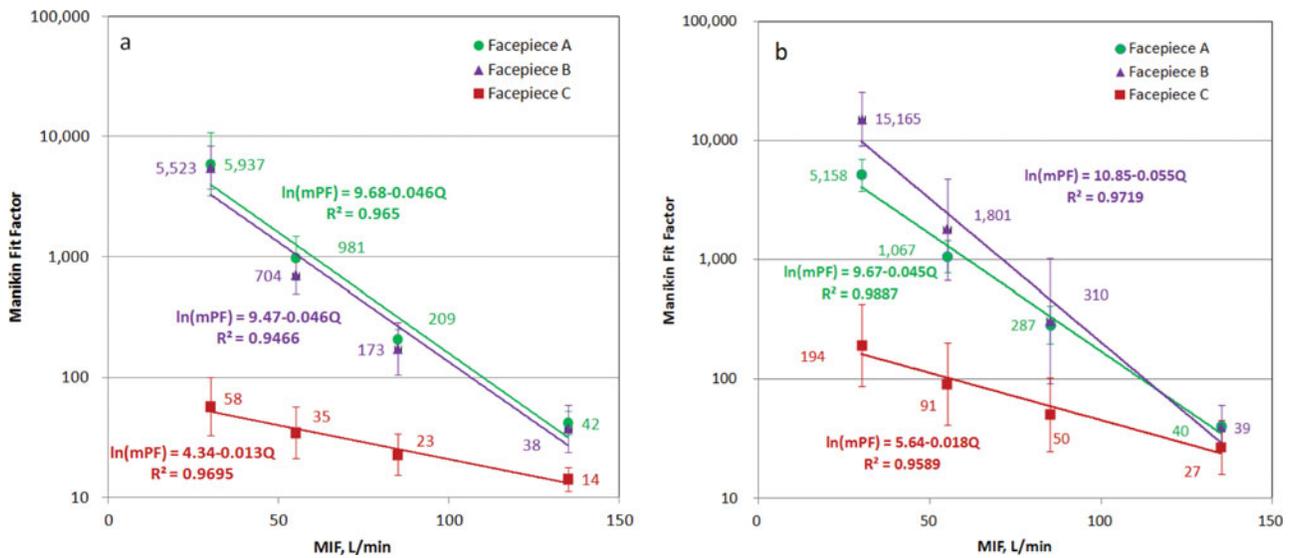
Figure 4. mFF as a function of MIF for three facepieces (a: exhaust holes uncovered; b: exhaust holes covered). Each point (with the number listed) represents the geometric mean of three replicate measurements, and the bars represent the geometric standard deviation.
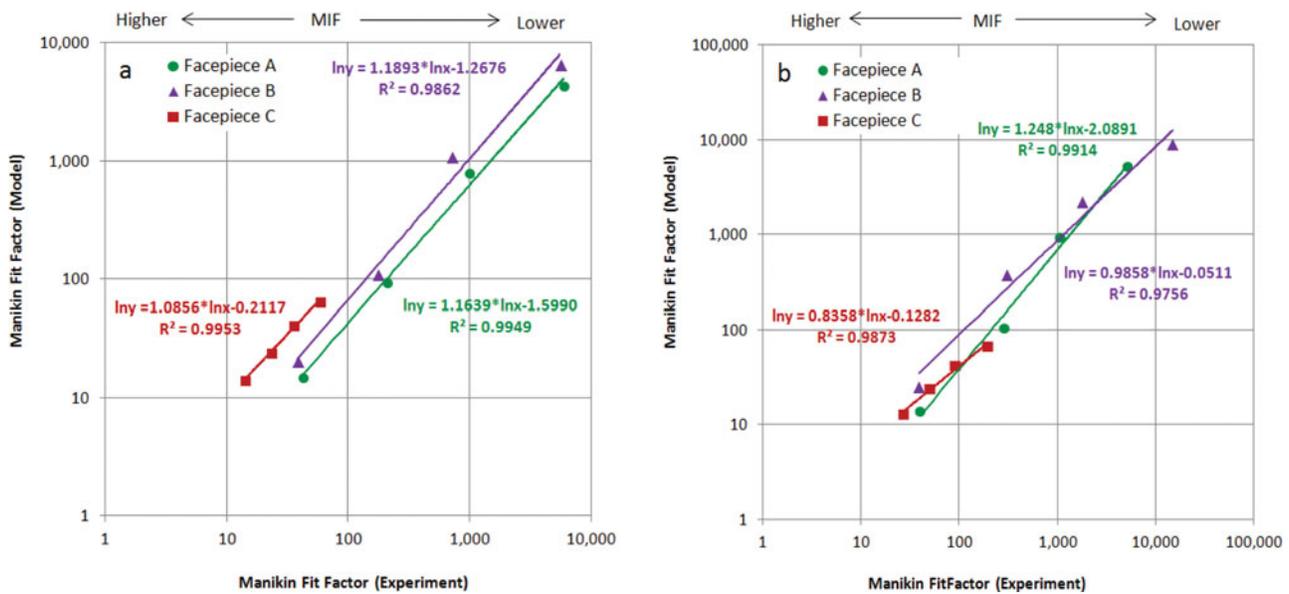

Figure 5. Correlation between calculated from constant flow regime (axis y) and experimentally determined under cyclic flow regime (axis x) mFF values (a: exhaust holes uncovered; b: exhaust holes covered). For each four-point data set (marked by a specific color), the points from left to right represent MIFs of 135, 85, 55, and 30 L/min.

the breathing time (inhalation). The numerical integration was performed by dividing the first half a period into 20 equal time segments so that the total penetration is determined as a time-weighted average.

Data analysis

SAS 9.3 (SAS Institute Inc, Cary, NC) was used to analyze the data. The mFF data were log-transformed before statistical analysis. The Geometric mean (GM) and the

Table 2. Three-way ANOVA results for the *ln(mFF)* as the function of facepiece type, MIF, and exhaust holes condition.

Source	DF	ANOVA SS	Mean Square	F Value	p-value
Facepiece type	2	32.13	16.07	26.71	< 0.01
MIF	3	52.65	17.55	29.18	< 0.01
Exhaust holes condition	1	1.70	1.70	2.83	0.11

DF, degrees of freedom; SS, sum of squares.

Table 3. ANOVA with post-hoc pairwise comparisons on the effect of facepiece type.

Facepiece Type	Facepiece Type	Estimate	SE	DF	T Value	p-value
B	A	0.12	0.88	21	0.14	0.89
B	C	2.51	0.88	21	2.86	0.01
A	C	2.39	0.88	21	2.73	0.01

SE, standard error; DF, degrees of freedom.

Table 4. Two-way ANOVA results for the *ln(mFF)* as the function of MIF and exhaust holes condition.

Facepiece Type	Source	DF	ANOVA SS	Mean Square	F Value	p-value
A	MIF	3	26.09	8.70	448.72	<0.01
	Exhaust holes condition	1	0.01	0.01	0.31	0.62
B	MIF	3	32.49	10.83	110.77	<0.01
	Exhaust holes condition	1	0.83	0.83	8.46	0.06
C	MIF	3	3.11	1.04	34.46	<0.01
	Exhaust holes condition	1	1.62	1.62	53.66	<0.01

DF, degrees of freedom; SS, sum of squares.

Geometric standard deviation (GSD) of mFF's values were calculated for each set of condition. A three-way analysis of variance (ANOVA) was used to evaluate the effect of facepiece type, MIF and exhaust holes condition on the mFF. ANOVA with post-hoc pairwise comparisons was conducted to test the difference between the mFFs of each paired facepiece. Two-way ANOVA was used to study the significance of MIF and exhaust holes condition for each individual facepiece. P-values less than 0.05 were considered to denote significant differences.

Results and discussion

Manikin protection factors

Figure 4 shows the mFF as a function of MIF for three tested facepieces. The mFF decreased exponentially with MIF increasing from 30 to 135 L/min. The experimentally determined mFF values ranged from 14–15,165. The highest mFF was observed at MIF = 30 L/min with Facepiece B while the lowest was found at MIF = 135 L/min with Facepiece C.

It is acknowledged that the mFFs obtained from the tests conducted using the manikin headform may overestimate the actual respiratory protection level in the field. When worn by respirator wearers, the facepiece may move given the continuous movement of the worker's head. This is particularly true when the blower hose does not swivel at the point of connection to the facepiece. There is no consensus to designate an acceptable level of protection when a loose fitting PAPR is configured to a manikin. However, the OSHA designated APF for this type of facepiece is 25. During fit testing, pass/fail criteria for tight-fitting negative pressure respirators is set at 10 times the APF. Consequently, another benchmark to evaluate PAPR performance would be to choose an mFF of 250 (10×25). Facepieces A (and B) had mFFs below 250 when the MIFs were greater than 90 L/min (and greater than 86 L/min for facepiece B) (see Figure 4a). Likewise, the performance of

these two facepieces was considerably lower when breathing flow rates corresponded to high and strenuous workloads. mFF values obtained for Facepiece C were below 250 for all tested MIFs. At MIF ≈ 85 L/min, the mFF fell even below 25. It was concluded that Facepiece C offered very little protection even under conditions of light exertion. Thus, we recommend that stretched-out facepieces should be removed from use in a workplace setting that requires respiratory protection.

Analysis of factors affecting mFF

Effect of facepiece type on mFF

As evident from Table 2, the effect of facepiece type on the performance of the loose-fitting PAPR was significant ($p < 0.01$). The mFFs of Facepiece C were significantly lower than those obtained for the other two facepieces ($p < 0.05$) while the difference between Facepieces A and B was not significant ($p > 0.05$, see Table 3). Facepiece C had the lowest mFF, followed by Facepieces A and B, suggesting that C offered the poorest fit on the manikin headform. This finding is consistent with our observations with respect to the size of the gap between the manikin face and facepiece, which was estimated to be approximately 19 cm^2, 22 cm^2, and 29 cm^2 for Facepieces A, B, and C, respectively. While a threshold for unacceptable gap size was not identified in this study, the data for Facepiece C supports the need to replace facepieces when the gap size is increased due to loss of elasticity. The protection factor of such "damaged" facepieces decreases because a bigger gap area allows more particles to penetrate into the facepiece.

Effect of MIF on mFF

The effect of MIF on mFF was significant ($p < 0.01$, see Table 2). As shown in Figure 4, an exponential regression trend line between MIFs and fit factors was fitted on all the experimental conditions. The coefficient of determination (R^2) ranged from 0.95–0.99, indicating a very good fit of the data to the regression lines. The mFF value decreased exponentially with the increasing MIF for all the tested facepieces (the regression equations are presented in Figure 4). First, this decrease was likely associated with a widening gap size between the face and the facepiece. With the breathing becoming more intense (higher MIF), the gap was observed to enlarge, which allowed more particles to enter. Second, clean air was delivered by the blower through the orifice, which was located in the middle of the forehead; this made the air flow directed to the nose and mouth area greater than the flow supplied to the cheek area; the latter created a pressure gradient that enhanced the particle penetration into the facepiece through the gap near the cheek area. This

Table 5. Three-way ANOVA results for the *ln(mFF)* as the function of facepiece type, constant inhalation flow rate, and exhaust holes condition.

Source	DF	ANOVA SS	Mean Square	F value	p-value
Facepiece type	2	68.19	34.09	46.68	< 0.01
Constant inhalation flow rate	11	708.18	54.48	74.58	< 0.01
Exhaust holes condition	1	0.11	0.11	0.16	0.69

DF, degrees of freedom; SS, sum of squares.

effect became more pronounced at higher breathing flow rates.

It should be emphasized that at MIF = 135 L/min, the calculated peak inspiratory flow (PIF) was 212 L/min, which exceeded the blower-delivered flow (198 L/min). This could cause a negative pressure inside of the facepiece over certain time intervals. The "over-breathing" caused by this negative pressure allowed the ambient particles to enter into the respirator, thus decreasing the protection factor. Although rare, PIF as high as 212 L/min could occur since instantaneous breathing flows over 400 L/min were reported by Mackey et al.[6]

Effect of exhaust holes on mFF

The three-way ANOVA performed for all facepieces combined revealed that exhaust holes condition did not significantly affect the mFF (p > 0.05, see Table 2). Under almost all the experimental conditions, the mFFs obtained with the exhaust holes covered were higher than those obtained with uncovered holes. The difference was significant only for Facepiece C (p < 0.05; see Table 4), which suggests that the effect of exhaust holes becomes more pronounced as the gap increases (see the change in p-values listed in "Exhaust holes condition" from Facepiece A to Facepiece C). One possible explanation is that a large gap around the chin may increase air turbulence through the exhaust holes by bringing in additional air and making the flow pattern inside more complex. Consequently, a greater particle

deposition could occur on surfaces around the holes. Thus, the effect of the exhaust holes with larger gap is significant.

Comparison of the calculated and experimentally-obtained mFFs under cyclic flow

The trends observed in the experiments conducted under both flow conditions (cyclic and constant) were mostly similar. The mFF decreased exponentially as the constant inhalation flows increased. In addition, significance of the effects of facepiece type and flow rate on the performance of the PAPR with a loose-fitting facepiece was confirmed for the constant flow regime (see Table 5). The effect of exhaust holes was equally complex for both cyclic and constant flow regimes; its significance depended on the facepiece type (see Table 6).

Figure 5 shows the relationships between the calculated and experimentally obtained mFFs under cyclic flow regime for all three facepieces and two exhaust holes conditions. A good correlation was observed in all cases. This suggests that the constant flow data can be used for predicting the protection within the range of 30–135 L/min offered by improperly sized, loose-fitting PAPRs under cyclic breathing conditions.

In general, it is more challenging to interpret the mFF trends and identify the mechanisms governing the particle penetration into a facepiece based on the data obtained under cyclic flow regime as compared to the "constant flow" results. Therefore, we used the experimental database obtained at Q = const (data not shown) to explain our findings on the protection provided by a loose-fitting PAPR. Under the constant flow regime, the airflow delivered by the blower was counteracted by the increased inhalation flow, resulting in increased air turbulence in the mouth and nose area of the manikin headform. The turbulence enhanced the mixing of particles and might have affected the particle transport through the faceseal gap and/or exhaust holes, thus influencing the measurement of mFF. This effect may particularly occur at deep breathing, thus negatively affecting the protection provided by an improperly sized, loose-fitting PAPR. Considering the complexity between cyclic and constant

Table 6. Two-way ANOVA results for the *Ln(mFF)* as the function of constant inhalation flow rate and exhaust holes condition.

Facepiece Type	Source	DF	ANOVA SS	Mean Square	F Value	p-Value
A	Constant inhalation flow rate	11	377.00	29.00	308.98	< 0.01
	Exhaust holes condition	1	0.00	0.00	0.00	0.97
B	Constant inhalation flow rate	11	341.09	26.24	118.70	< 0.01
	Exhaust holes condition	1	1.17	1.17	5.28	0.027
C	Constant inhalation flow rate	11	67.61	5.20	13.40	< 0.01
	Exhaust holes condition	1	2.82	2.82	7.27	0.01

DF, degrees of freedom; SS, sum of squares.

inhalation flow patterns, the similarity in mFF is remarkable.

Limitation

This study was limited to three loose-fitting facepieces of the same brand. Additionally, it focused only on loose-fitting PAPR facepieces, which were improperly sized. Further research is needed to examine the performance of the same loose-fitting PAPRs when they are properly sized to the wearers.

Conclusion

Based on the manikin-based testing of the two undamaged loose-fitting PAPR facepieces, the mFF decreased exponentially with increasing MIFs revealing rather low mFFs at high MIFs. These two facepieces provided relatively low protection (mFFs <250) at breathing flow rates corresponded to high and strenuous workloads. The mFF values of the stretched-out loose-fitting facepiece were significantly lower than those obtained for the undamaged facepieces; the former are unlikely to provide an acceptable level of protection even at a moderate workload. Facepiece type and MIF were significant factors affecting the performance of the loose-fitting PAPRs. The effect of the exhaust holes condition was less significant and depended on the facepiece type. The model utilizing integrated mFF data obtained under constant flow regime is capable of predicting the protection offered by improperly sized, loose-fitting PAPRs under cyclic breathing conditions. The results of this study suggest that respirator program administrators should ensure that loose-fitting facepieces are properly sized to employees and remove stretched-out facepieces from the workplace.

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