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Evaluation of N95 Respirator Use with a Surgical Mask Cover: Effects on Breathing Resistance and Inhaled Carbon Dioxide

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Objective: For pandemic influenza outbreaks, the Institute of Medicine has recommended using a surgical mask cover (SM) over N95 filtering facepiece respirators (FFRs) among healthcare workers as one strategy to avoid surface contamination of the FFR which would extend its efficacy and reduce the threat of exhausting FFR supplies. The objective of this investigation was to measure breathing air quality and breathing resistance when using FFRs with US Food and Drug Administration-cleared SM and without SM.

Methods: Thirty National Institute for Occupational Safety and Health (NIOSH)-approved FFR models with and without SM were evaluated using the NIOSH Automated Breathing and Metabolic Simulator (ABMS) through six incremental work rates.

Results: Generally, concentrations of average inhaled CO_2 decreased and average inhaled O_2 increased with increasing O_2 consumption for FFR+SM and FFR-only. For most work rates, peak inhalation and exhalation pressures were statistically higher in FFR+SM as compared with FFR-only. The type of FFR and the presence of exhalation valves (EVs) had significant effects on average inhaled CO_2, average inhaled O_2, and breathing pressures. The evidence suggests that placement of an SM on one type of FFR improved inhaled breathing gas concentrations over the FFR without SM; the placement of an SM over an FFR+EV probably will prevent the EV from opening, regardless of activity intensity; and, at lower levels of energy expenditure, EVs in FFR do not open either with or without an SM.

Conclusions: The differences in inhaled gas concentrations in FFR+SM and FFR-only were significant, especially at lower levels of energy expenditure. The orientation of the SM on the FFR may have a significant effect on the inhaled breathing quality and breathing resistance, although the measurable inhalation and exhalation pressures caused by SM over FFR for healthcare users probably will be imperceptible at lower activity levels.

Keywords: breathing resistance; effects from using N95 respirators; extending N95 respirators during influenza outbreak; inhaled carbon dioxide; inhaled oxygen; metabolic simulator; N95 respirator; respiratory protection; surgical mask; using N95 respirators with surgical or procedure masks

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INTRODUCTION

At the request of the Department of Health and Human Services, the Institute of Medicine (IOM) convened a Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic in order to report on the solutions, limitations, threats, and possible opportunities of reusing respirators for infection control during an influenza pandemic (Institute of Medicine and Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic, 2006). The Committee offered recommendations for extending the life of disposable N95 filtering facepiece respirators (FFRs) for individual users. One recommendation involved placing a surgical mask cover (SM) over the respirator in order to prevent respirator surface contamination. Previous studies have reported elevated concentrations of inhaled carbon dioxide (CO_2) and decreased concentrations of inhaled oxygen (O_2) associated with wearing FFRs (Sinkule *et al.*, 2003). Others have proposed that the adverse effects of wearing FFRs (e.g., headache and increased sick days) are the result of elevated inhaled CO_2 concentrations (Lim *et al.*, 2006). The increased inhaled CO_2 concentrations and decreased inhaled O_2 concentrations within the breathing zone of negative-pressure air-purifying respirators, including FFRs, are directly related to dead space. Changes resulting from the addition of an US Food and Drug Administration (FDA)-cleared surgical mask could include increased levels of CO_2, breathing resistance, and temperature of inspired air, and decreased levels of O_2. National Institute for Occupational Safety and Health (NIOSH) certification tests that measure minimum and average inhaled CO_2 concentrations, and maximum and average inhaled O_2 concentrations, apply only to respirators certified for protection against chemical, biological, radiological, or nuclear (CBRN) hazards. A European test standard (EN 149:2001) characterizes inhaled CO_2 concentration and breathing resistance, among other assessments from FFR use.

The effects of wearing FFRs and other types of respiratory protection have been widely studied using a variety of measurement methods (Li *et al.*, 2005; Radonovich *et al.*, 2009; Roberge *et al.*, 2010). Some of these investigations have been quantitative (e.g., levels of inhaled CO_2), qualitative (e.g., levels of fatigue), or can reflect characteristics that range from inconvenient (e.g., decreased levels of comfort) to potentially hazardous (e.g., decreased inhaled levels of O_2). The physiological effects of breathing elevated inhaled CO_2 may include changes in visual performance (Yang *et al.*, 1997), modified exercise endurance (Raven *et al.*, 1979), headaches and dyspnea (Raven *et al.*, 1979). The psychological effects include decreased reasoning and alertness, and increased irritability (Sayers *et al.*, 1987); with CO_2 at 7–7.5%, severe dyspnea, headache, dizziness, perspiration, and short-term memory loss have been reported (Sayers *et al.*, 1987; Compressed Gas Association, 1999). Subjects performing physical activity while breathing decreased O_2 concentrations (17%) produced higher levels of lactic acid accumulation at lower levels of energy expenditure as compared with normal O_2 concentrations (21%), in addition to achieving lower levels of peak exercise performance (Hogan *et al.*, 1983). Increased breathing resistance with respirators has been identified as the cause of respiratory fatigue and impaired physical work capacity, a shift to anaerobic metabolism from an increased rate of O_2 debt; and, early exhaustion at lighter workloads.

To date, no laboratory or field studies have been published to provide data on the effect of protective covers (e.g., surgical masks) on the breathing pressures and concentrations of inhaled respiratory gases among multiple models and types of FFRs, including many matched FFR models paired with and without exhalation valves (EVs). The major purpose of this study was to evaluate the inhaled CO_2 and O_2 concentrations and breathing pressures of NIOSH-certified FFRs with and without an SM using an Automated Breathing and Metabolic Simulator (ABMS)-based test. An ABMS test protocol was used to characterize performance in terms of minimum and average inhaled CO_2 concentrations, maximum and average inhaled O_2 concentrations, and inhalation and exhalation pressures. The evaluations were repeated with identical FFRs worn with an SM.

METHODS

Respirator and surgical mask selection

The selection of NIOSH-certified FFR models used for this study was determined by market analysis, with a focus on those FFR models in the US Strategic National Stockpile (SNS) at the time of this investigation (US Department of Health and Human Services, 2009). None of the FFRs in the SNS had EVs. In order to evaluate both conditions, FFRs without and with EVs were included in this study. No assumptions were made regarding the materials or construction details of the entire sample of FFRs, including EVs, FFR fabric, or head straps. The SM model was a device also identified as being in the SNS. A sample of at least four respirators of a consistent common size (medium, medium/large, or universal) among each the following types was tested in the present investigation: N95 cup, N95 horizontal flat-fold, and N95 other flat-fold. The N-series FFR is restricted for use in workplaces free of oil aerosols, and 95 means the filter device is 95% efficient for filtering a mean particle size up to 0.075 ± 0.020 µm. The type of FFR (for example, cup or horizontal flat-fold) is a manufacturer designation and is not a classification or differentiation in a NIOSH standard.

A consistent common size in FFR does not mean the same dead space. Constructional differences between the different types of FFRs complicated the characterization of dead space even further. In the sample of FFRs used in this investigation, including those from the SNS, "medium"-sized FFRs were selected when various sizes were available. Size specifications for several FFRs, however, included intermediate sizes, such as, "one-size-fits-all" (also known as "universal size") and "medium/large" sizes. Intermediate sizes and manufacturer-specific FFRs were unbalanced among respirator models between FFRs with and without EVs. Furthermore, as there are no federal regulations or industry standards for sizing FFRs, dissimilar sizes between manufacturers would occur and would affect respirator dead space. Comparison of respirator dead space among the various respirators, therefore, may not be meaningful for individual FFR performance. In the paired-valve FFR subset, manufacturer-specific respirators and sizes between FFRs with and without EVs were the same, i.e. balanced among the respirator models. It was necessary to include a variety of manufacturers for the sample in order to ensure that a representative market sample was evaluated (see Table 1).

Thirty NIOSH-approved FFR models and one flat-fold SM model were selected for this investigation. The FFR sample represented approximately 10% of the 300+ NIOSH-approved FFR models (National Institute for Occupational Safety and Health, 2011). Table 1 provides the grouping among the respirator models for each type and the presence of an EV. The SM used was Medline NON27382, which was also in the SNS. This SM was a random selection between two SMs available from the SNS that did not have ear loops for attachments thus compatible with a head form without ears. Among the 30 respirator models, 18 were of the cup type, six of the horizontal flat-fold type, and six of the other flat-fold type. The "other flat-fold" types included three vertical flat-fold and three tri-fold respirators. The results were grouped by manufacturer's classification and the relative number of models (see Table 1) in each group. Eighteen respirator models (five cup pairs, two horizontal flat-fold pairs, and two other flat-fold pairs) were paired-valve models, that is, the same respirator except one with and one without an EV.

Table 1. Grouping of the FFR type and valve.

FFR type	FFR without exhalation valve	FFR with exhalation valve
Cup	3M 1860 (M)[a]	3M 8211 (O)
	3M 8000 (O)[a]	3M 8212 (O)
	3M 8210 (O)[a]	3M 8511 (O)
	Inovel 3002 (M)[a]	3M 8512 (O)
	AO Safety N9504C (O)[b]	AO Safety N9505C (O)[b]
	Crews RPN951 (O)[b]	Crews RPN952 (O)[b]
	Gerson 1730 (O)[a,b]	Gerson 1740 (O)[b]
	Moldex 2200 (M/L)[a,b]	Moldex 2300 (M/L)[b]
	Moldex-Metrics 2600 (M/L)[b]	Moldex-Metrics 2700 (M/L)[b]
Horizontal	Kimberly-Clark 46727 (O)[a]	Willson N9520FM (M)
Flat-fold	Crews RPFN951 (O)[b]	Crews RPFN952 (O)[b]
	San Huei SH2950 (O)[b]	San Huei SH2950V (O)[b]
Other	3M 1870 (O)[a]	Dräger Piccola (O)
Flat-fold	3M 9210 (O)[a,b]	3M 9211 (O)[b]
	San Huei SH3500 (O)[b]	San Huei SH3500V (O)[b]

Respirators are FFR (size).
M, medium size; M/L, medium/large size; O, one-size-fits-all/universal size.
[a]Selected FFR from the Strategic National Stockpile.
[b]Paired-valve respirators: the same FFR with or without an exhalation valve.

Automated breathing and metabolic simulator

The ABMS is ideal for quantitative and repeatable testing and evaluation of FFRs. The ABMS (Ocenco, Inc., Pleasant Prairie, WI) has the capability to simulate the following human metabolic parameters: O_2 consumption, CO_2 production, respiratory frequency, tidal volume, breathing waveform shape, and heated and humidified exhaled breathing gas. In addition, any number of work rates may be serially combined in any order to simulate various activities. The capacity ranges for the parameters are as follows: minute ventilation, 0–160 $l{\cdot}min^{-1}$; O_2 consumption, 0–7 $l{\cdot}min^{-1}$; CO_2 production, 0–7 $l{\cdot}min^{-1}$; respiratory frequency, 0–100 $breaths{\cdot}min^{-1}$; tidal volume, 0–5 l; and human-like breathing gas temperatures, 30–45°C. All gas volume parameters were at standard conditions of temperature (0°C), pressure (760 mmHg), and dry (no water vapor) unless indicated otherwise. A sinusoid waveform was used for ventilation rates below 50 $l{\cdot}min^{-1}$. A trapezoid or human-like waveform was used for ventilation rates above 50 $l{\cdot}min^{-1}$.

The ABMS is capable of monitoring the following variables: flow-weighted average inhaled concentrations of O_2 and CO_2, minimum inhaled CO_2 concentration, maximum inhaled O_2 concentration, breathing pressures, and inhaled dry-bulb and wet-bulb gas temperatures. The capacity ranges for these parameters are as follows: O_2 concentration, 0–100%; CO_2, 0–15%; breathing pressure, ±700 mm of water (H_2O); and inhaled dry-bulb and wet-bulb gas temperatures, 0–100°C. The results of this investigation only will report the average inhaled CO_2 and O_2 concentrations, and peak inhalation and exhalation pressures. A more detailed explanation is given in the appendix of the US Bureau of Mines publication by Kyriazi (1986). Deno (1984) provides a description of the development of the ABMS. There has been one research report where the responses from the ABMS with air-purifying CBRN escape hoods were shown to be very similar to responses from human subject volunteers, although a statistical comparison between the ABMS and human subjects was not conducted (Sinkule and Turner, 2004).

Experimental design and variables

Each week, FFR testing was preceded by instrument calibration (pressure transducer, dry-bulb thermocouple, and wet-bulb thermocouple) and routine room air validation studies. Before each test, the fast-response ABMS gas analyzers were calibrated using primary standard calibration gases (15% O_2 and 8% CO_2), when response time (<100 ms) and transport time were calculated (<300 ms) and used to electronically offset sample time. Prior to attaching the FFR, a leak test was performed on the ABMS. According to the manufacturers' instructions, respirators were then placed on a head form attached to the trachea of the ABMS. A sealant (Poli-Grip®) was applied to the contact area between the head form and FFR in order to create a seal between the facial surface of the head form with each FFR. The face seal with a NIOSH-approved FFR among human users is assessed with a fit-test. No sealant was used while donning an SM to the FFR since a fit-test is not needed for using surgical masks. FFRs, with or without SM, were tested for a minimum of 5 min at each work rate.

The breathing frequencies (*f*), tidal volumes (V_T), minute ventilation rates ($\dot{V}_E$), O_2 consumption rates ($\dot{V}O_2$), CO_2 production rates ($\dot{V}CO_2$), and respiratory quotients (*R*) programmed into the ABMS are shown in Table 2. These metabolic rates represent a progression from light to very intense energy expenditures. For healthcare workers, the range of energy expenditure can be from very light (e.g. desk work used for writing patient notes, 1.8 METs; or performing procedures in an operating room, 3 METs) to moderate (e.g. moving patients 34 kilograms or more, 7.5 METs) to very intense (e.g. responding to emergency calls by paramedics, patient care by physical therapists, and emergency calls performed by

Table 2. Metabolic variables for the ABMS exercise protocol.

Test level	*f* (breath/min)	V_T (l, BTPS)	$\dot{V}_E$ ($l{\cdot}min^{-1}$, BTPS)	$\dot{V}O_2$ ($l{\cdot}min^{-1}$, STPD)	$\dot{V}CO_2$ ($l{\cdot}min^{-1}$, STPD)	*R*
1	12.9	0.92	11.9	0.5	0.4	0.80
2	19.5	1.57	30.6	1.0	0.8	0.80
3	28.0	1.63	45.6	1.5	1.3	0.87
4	32.6	2.30	75.0	2.0	1.9	0.95
5	34.2	2.42	82.8	2.5	2.5	1.00
6	36.4	2.66	96.8	3.0	3.15	1.05

(f=frequency of breathing; V_T=tidal volume; $\dot{V}_E$=minute ventilation, expired; $\dot{V}O_2$=oxygen consumption; $\dot{V}CO_2$=carbon dioxide production; R=respiratory quotient; BTPS=volumes expressed at body temperature (37ºC), ambient pressure, and saturated with water vapor.)

flight nurses, >10 METs) (Ainsworth *et al.*, 2000). One MET (metabolic equivalent) is equal to a resting metabolic rate equal to quiet sitting, or 3.5 ml of oxygen consumed·kg^{-1}·min^{-1}.

In a randomized fashion, selected models of FFRs and the same models of FFRs with a selected SM were evaluated as the test conditions. Flow-weighted average inhaled CO_2 and O_2 concentrations as well as peak and average inhaled and exhaled pressures at the mouth were measured by the ABMS, and arithmetic means of these variables were calculated. The data during the last minute of each variable at each level of energy expenditure (Table 2) for each condition (FFRs only and FFRs with SM) were used for analysis.

Data from a previous NIOSH study that investigated the inhaled CO_2 concentrations in various respirators using the ABMS were used to determine sample sizes in the current study (Sinkule *et al.*, 2003). The mean fractional minimal inhaled CO_2 concentration was 0.25%, the within-group, or within-respirator standard deviation (pooled over the different units) was 0.09%. The between-group variability represented 94.4% of the overall variability in CO_2 measurements. For the initial power estimate, the analysis of variance contrast between those with and without an SM will have similar power to the two-sample *t*-test with a pooled standard deviation of 0.09% and a sample size of $n = 0.944 \times 96$, which (conservatively) ≈90 per group. The sample size, therefore, of at least four respirators of each model was tested for 5 min at each oxygen consumption rate, both with and without an SM. A total of 281 trials were completed, or an average of 4.7 trials for each respirator model tested with and without an SM.

Dependent variables (average inhaled CO_2 concentrations, average inhaled O_2 concentrations, and peak inhalation and exhalation pressures) were analyzed using 2 × 2 × 3 (SM × EV × FFR type) factorial analysis of variance (ANOVA). For each dependent variable, comparisons between the treatments (SM versus no SM) were performed for respirators with and without EVs and for each type of FFR (cup, horizontal flat-fold, and other flat-fold). The Tukey multiple comparison test was used for all *post hoc* analysis of significant effects. Statistical significance for ANOVA and Tukey analyses was set *a priori* at $P < 0.05$. Data analyses were performed using SPSS, version 17 (SPSS, Inc., Chicago, IL, USA).

RESULTS

Respiratory gases

Results for the average inhaled CO_2 concentration among FFRs with and without SM are shown in Table 3. Among the six levels of energy expenditure, the average inhaled CO_2 concentrations were higher ($P < 0.05$) among the cup FFRs with SM as compared with cup FFRs alone at $\dot{V}O_2$ of 0.5 l·min^{-1}, 2.5 l·min^{-1}, and 3.0 l·min^{-1}. The average inhaled CO_2 concentrations were lower ($P < 0.05$) among horizontal flat-fold FFRs with SM as compared with horizontal flat-fold FFRs alone at $\dot{V}O_2$ of 1.0 l·min^{-1} and 1.5 l·min^{-1}. The average inhaled CO_2 concentrations were not different between other flat-fold FFRs with and without SM. Significant interactions ($P < 0.05$) between FFR type and SM use on average inhaled CO_2 were observed for $\dot{V}O_2$ of 1.0 l·min^{-1},

Table 3. Average inhaled carbon dioxide concentrations (%) among FFRs with and without SM.

Oxygen consumption (l·min^{-1})	Treatment	Cup (n = 18)	Horizontal Flat-fold (n = 6)	Other Flat-fold (n = 6)
0.5	FFR only	2.49 ± 0.51	3.52 ± 0.93	2.65 ± 0.57
	FFR + SM	2.93 ± 0.38*	3.14 ± 0.64	3.13 ± 0.40
1.0	FFR only	1.64 ± 0.53	2.87 ± 1.12	1.93 ± 0.66
	FFR + SM	1.98 ± 0.39	2.00 ± 0.44*	2.01 ± 0.12
1.5	FFR only	2.09 ± 0.82	3.23 ± 1.32	2.31 ± 0.94
	FFR + SM	2.31 ± 0.41	2.30 ± 0.46*	2.21 ± 0.09
2.0	FFR only	1.43 ± 0.60	1.81 ± 0.82	1.65 ± 0.73
	FFR + SM	1.75 ± 0.33	1.67 ± 0.33	1.58 ± 0.15
2.5	FFR only	1.28 ± 0.57	1.66 ± 0.77	1.52 ± 0.73
	FFR + SM	1.65 ± 0.38*	1.52 ± 0.26	1.48 ± 0.16
3.0	FFR only	1.52 ± 0.65	1.90 ± 0.87	1.79 ± 0.89
	FFR + SM	1.99 ± 0.33*	1.75 ± 0.32	1.71 ± 0.22

Values are means ± SD.
*Significantly different from FFR only, $P < 0.05$.

2.5 $l\cdot min^{-1}$, and 3.0 $l\cdot min^{-1}$; between FFRs with EVs and SM use at $\dot{V}O_2$ of 1.5–3.0 $l\cdot min^{-1}$.

Results for the average inhaled O_2 concentration among FFRs with and without SM are presented in Table 4. Among the six levels of energy expenditure, the average inhaled O_2 concentrations were lower ($P < 0.05$) among the cup FFRs with SM as compared with cup FFRs alone at $\dot{V}O_2$ of 0.5 $l\cdot min^{-1}$, 2.5 $l\cdot min^{-1}$, and 3.0 $l\cdot min^{-1}$. The average inhaled O_2 concentrations were higher ($P < 0.05$) among horizontal flat-fold FFR with SM as compared with horizontal flat-fold FFRs alone at $\dot{V}O_2$ of 1.0 $l\cdot min^{-1}$ and 1.5 $l\cdot min^{-1}$. The average inhaled O_2 concentrations were not different between other flat-fold FFRs with and without SM. Significant interactions ($P < 0.05$) between FFR type and EV on average inhaled O_2 concentration were observed for $\dot{V}O_2$ of 0.5 $l\cdot min^{-1}$ only; between FFR type and SM use on average inhaled O_2 for $\dot{V}O_2$ of 1.0 $l\cdot min^{-1}$, 1.5 $l\cdot min^{-1}$, and 3.0 $l\cdot min^{-1}$; between FFRs with EVs and SM use at $\dot{V}O_2$ of 1.5–3.0 $l\cdot min^{-1}$.

Breathing pressures

Peak inhalation and exhalation pressures are used as measures of breathing resistance among respirator users. Results for peak exhalation pressure among FFRs with and without SM are presented in Table 5. Among the six levels of energy expenditure, the peak exhalation pressures were higher ($P < 0.05$) among the cup FFRs with SM as compared with cup FFRs alone at $\dot{V}O_2$ of 1.5 $l\cdot min^{-1}$, 2.0 $l\cdot min^{-1}$, 2.5 $l\cdot min^{-1}$, and 3.0 $l\cdot min^{-1}$. Peak exhalation pressures were not different between horizontal flat-fold FFRs with or without SM, or between other flat-fold FFRs with or without SM. In addition, a significant ($P < 0.05$) main effect of SM use and FFRs with an EV on peak exhalation pressure was observed for $\dot{V}O_2$ of 1.5–3.0 $l\cdot min^{-1}$.

Results for peak inhalation pressure among FFRs with and without SM are presented in Table 6. Among the six levels of energy expenditure, the peak inhalation pressures were higher ($P < 0.05$) among the cup FFRs with SM as compared with cup FFRs alone at every level of O_2 consumption. Peak inhalation pressures were different between other flat-fold FFRs with or without SM at $\dot{V}O_2$ of 2.0 $l\cdot min^{-1}$, 2.5 $l\cdot min^{-1}$, and 3.0 $l\cdot min^{-1}$. Peak inhalation pressures were not different between horizontal flat-fold FFRs with and without SM. In addition, a significant ($P < 0.05$) main effect of SM use on peak inhalation pressure was observed for $\dot{V}O_2$ of 1.0–3.0 $l\cdot min^{-1}$.

The presence of an EV is intended to affect breathing resistance by reducing exhalation pressure. Fifteen of the 30 FFR models contained an EV. The EV is a flexible dam (usually made of rubber) anchored to a circular frame that is mounted in the wall of the FFR directly in the front of the breathing zone. Upon negative mask pressure created by inhalation, the flexible dam is pulled into its frame to create a seal and prevent air leaking into the FFR mask. Table 7 contains results of peak inhalation and exhalation pressures in FFRs with and without EVs as compared with FFRs with and without SM.

Paired-valve FFR models

Eighteen paired-valve FFR models (five pairs of cup, two pairs of horizontal flat-fold, and two pairs of other flat-fold) provided a homogeneous subset for

Table 4. Average inhaled oxygen concentrations (%) among FFRs with and without SM.

Oxygen consumption ($l\cdot min^{-1}$)	Treatment	Cup (n = 18)	Horizontal Flat-fold (n = 6)	Other Flat-fold (n = 6)
0.5	FFR only	17.40 ± 0.81	16.10 ± 1.14	17.31 ± 0.77
	FFR + SM	16.81 ± 0.54*	16.52 ± 0.79	16.58 ± 0.67
1.0	FFR only	18.84 ± 0.77	17.30 ± 1.39	18.47 ± 0.89
	FFR + SM	18.39 ± 0.50	18.39 ± 0.55*	18.29 ± 0.17
1.5	FFR only	18.49 ± 1.04	17.15 ± 1.52	18.22 ± 1.13
	FFR + SM	18.22 ± 0.49	18.25 ± 0.51*	18.25 ± 0.09
2.0	FFR only	19.33 ± 0.70	18.92 ± 0.84	19.08 ± 0.84
	FFR + SM	18.96 ± 0.37	19.05 ± 0.35	19.05 ± 0.15
2.5	FFR only	19.52 ± 0.65	19.12 ± 0.77	19.26 ± 0.82
	FFR + SM	19.11 ± 0.41*	19.25 ± 0.28	19.19 ± 0.16
3.0	FFR only	19.32 ± 0.71	18.95 ± 0.83	19.03 ± 0.96
	FFR + SM	18.82 ± 0.38*	19.06 ± 0.34	18.98 ± 0.23

Values are means ± SD.
*Significantly different from FFR only, $P < 0.05$.

Table 5. Peak exhalation pressures (mmH_2O) among FFRs with and without SM.

Oxygen consumption ($l{\cdot}min^{-1}$)	Treatment	Cup (*n* = 18)	Horizontal Flat-fold (*n* = 6)	Other Flat-fold (*n* = 6)
0.5	FFR only	8 ± 2	7 ± 2	7 ± 4
	FFR + SM	8 ± 2	8 ± 2	9 ± 3
1.0	FFR only	10 ± 3	11 ± 3	9 ± 3
	FFR + SM	12 ± 3	12 ± 3	11 ± 2
1.5	FFR only	14 ± 4	15 ± 3	14 ± 4
	FFR + SM	17 ± 4*	18 ± 4	17 ± 2
2.0	FFR only	23 ± 7	24 ± 4	22 ± 6
	FFR + SM	29 ± 7*	30 ± 8	28 ± 4
2.5	FFR only	20 ± 6	21 ± 4	19 ± 5
	FFR + SM	25 ± 6*	26 ± 6	24 ± 4
3.0	FFR only	24 ± 8	25 ± 4	23 ± 6
	FFR + SM	30 ± 7*	31 ± 8	29 ± 4

Values are means ± SD.
*Significantly different from FFR only, $P < 0.05$.

Table 6. Peak inhalation pressures (mmH_2O) among FFRs with and without SM.

Oxygen consumption ($l{\cdot}min^{-1}$)	Treatment	Cup (*n* = 18)	Horizontal Flat-fold (*n* = 6)	Other Flat-fold (*n* = 6)
0.5	FFR only	−6 ± 1	−5 ± 2	−6 ± 2
	FFR + SM	−7 ± 2*	−6 ± 2	−7 ± 1
1.0	FFR only	−12 ± 2	−12 ± 4	−12 ± 2
	FFR + SM	−15 ± 3*	−14 ± 5	−14 ± 2
1.5	FFR only	−19 ± 4	−19 ± 6	−18 ± 2
	FFR + SM	−23 ± 5*	−23 ± 8	−23 ± 3
2.0	FFR only	−35 ± 6	−34 ± 10	−33 ± 3
	FFR + SM	−41 ± 7*	−43 ± 16	−44 ± 11*
2.5	FFR only	−35 ± 6	−34 ± 10	−33 ± 3
	FFR+ SM	−42 ± 8*	−44 ± 16	−45 ± 12*
3.0	FFR only	−41 ± 7	−42 ± 13	−40 ± 3
	FFR + SM	−49 ± 9*	−54 ± 22	−56 ± 17*

Values are means ± SD.
*Significantly different from FFR only, $P < 0.05$.

analyses. Where the main sample of FFR represented a variety of respirator shapes across the different FFR types (cup, horizontal flat-fold, and other flat-fold) for those with and without EVs, the subset of paired-valve FFR represented identical FFRs, with and without EVs.

Figure 1 illustrates the effects of EVs on the average inhaled CO_2 concentration among FFRs with and without SM. The bars are the mean difference (delta) of the average inhaled CO_2 concentration in FFRs with EVs and the average inhaled CO_2 concentration in FFRs without EVs. The black filled bars are the delta CO_2 concentrations among FFRs without SM. The white filled bars are the delta CO_2 concentrations among FFRs with SM. From Figure 1 it can be seen that FFRs with a SM (light bars) produced small and similar delta values in average inhaled CO_2 concentrations among a spectrum of energy expenditures in the matched models of FFRs paired with and without EVs, and there were no significant differences in the delta values of average inhaled CO_2 between FFRs and FFR+SM among the matched models of FFRs paired with and without EVs below $\dot{V}O_2$ of 1.5 $l{\cdot}min^{-1}$. A significant ($P < 0.05$) main effect was observed with SM use at $\dot{V}O_2$ of 1.5 $l{\cdot}min^{-1}$ for average inhaled CO_2. Significant interactions ($P < 0.05$) between FFR type and SM use on average inhaled CO_2 concentration

Table 7. Peak inhalation and exhalation pressures (mmH_2O) among FFRs with and without EV between FFRs with and without SM.

Oxygen consumption ($l \cdot min^{-1}$)	Treatment	Peak inhalation pressure FFR − EV	Peak inhalation pressure FFR + EV	Peak Exhalation Pressure FFR − EV	Peak Exhalation Pressure FFR + EV
0.5	FFR only	−6 ± 1	−5 ± 2	7 ± 2	8 ± 2
	FFR + SM	−7 ± 2	−7 ± 2*	8 ± 2	8 ± 3
1.0	FFR only	−11 ± 2	−12 ± 3	11 ± 3	10 ± 3
	FFR + SM	−14 ± 3*	−15 ± 4*	13 ± 2*	10 ± 3
1.5	FFR only	−18 ± 3	−20 ± 4	16 ± 4	13 ± 4
	FFR + SM	−22 ± 4*	−24 ± 6*	19 ± 3*	15 ± 3
2.0	FFR only	−33 ± 5	−36 ± 8	27 ± 6	20 ± 5
	FFR + SM	−40 ± 8*	−45 ± 11*	33 ± 6*	25 ± 5*
2.5	FFR only	−33 ± 5	−36 ± 8	23 ± 5	17 ± 5
	FFR + SM	−40 ± 8*	−45 ± 12*	28 ± 5*	22 ± 4*
3.0	FFR only	−39 ± 5	−43 ± 9	27 ± 6	20 ± 6
	FFR + SM	−49 ± 12*	−54 ± 15*	34 ± 6*	26 ± 5*

Values are means ± SD.
*Significantly different from FFR only, $P < 0.05$.

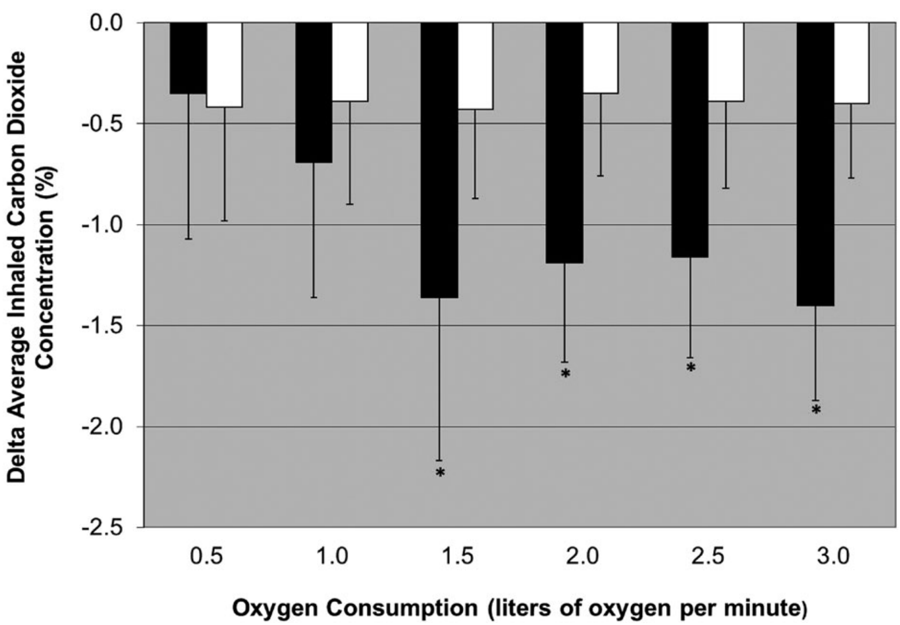

Fig. 1. Average inhaled CO_2 delta (FFR with exhalation valve minus FFR without exhalation valve) concentrations (mean ± SD) in FFR with and without surgical mask covers for all levels of oxygen consumption. FFR without surgical mask covers (FFR only) = black bars, FFR with surgical mask covers (FFR+SM) = white bars. *Significantly different from FFR+SM, $P < 0.05$.

were observed for $\dot{V}O_2$ of 0.5 $l \cdot min^{-1}$, 1.0 $l \cdot min^{-1}$, 1.5 $l \cdot min^{-1}$, and 3.0 $l \cdot min^{-1}$; between FFRs with EV and SM use on average inhaled CO_2 concentration observed at $\dot{V}O_2$ of 1.5–3.0 $l \cdot min^{-1}$.

Figure 2 illustrates the effects of EVs on the average inhaled O_2 concentration among FFRs with and without SM. The bars are the mean difference (delta) of the average inhaled O_2 concentration in FFRs with EVs and the average inhaled O_2 concentration in FFRs without EVs. The black filled bars are the delta O_2 concentrations among FFRs without SM. The white filled bars are the delta O_2 concentrations among FFRs with SM. Like the conclusions presented for Figure 1 (average inhaled CO_2), FFRs with an SM (light bars) produced small and similar delta values in average inhaled O_2 concentrations among a spectrum of energy expenditures in the matched models of FFRs paired with and without EVs, and there were no significant differences in the delta values of average inhaled O_2 between FFRs and FFR+SM among the matched models of FFRs paired with and without EVs below $\dot{V}O_2$ of 1.5 l·min^{-1}. Significant interactions ($P < 0.05$) between FFR type and SM use on average inhaled O_2 concentration were observed for $\dot{V}O_2$ of 0.5 l·min^{-1}, 1.0 l·min^{-1}, and 1.5 l·min^{-1}, and 3.0 l·min^{-1}; and, between FFR with EV and SM use on average inhaled O_2 concentration observed at $\dot{V}O_2$ of 1.5 l·min^{-1}, 2.0 l·min^{-1}, 2.5 l·min^{-1}, and 3.0 l·min^{-1}.

For both peak inhalation and peak exhalation pressures, the delta values between the FFRs with and without EVs were not different for the FFRs and FFR+SM. A significant ($P < 0.05$) main effect of SM use was observed for peak exhalation pressure at $\dot{V}O_2$ of 1.5–3.0 l·min^{-1}. A significant ($P < 0.05$) main effect of SM use on peak inhalation pressure was observed for $\dot{V}O_2$ of 1.0–3.0 l·min^{-1}.

DISCUSSION

Respiratory gases

Respirator scientists have known that respiratory protection may have adverse effects on breathing pressures from restricted flow characteristics and inhaled CO_2 and O_2 concentrations from increased dead space. Increased dead space causes an increase in tidal volume and respiratory rate (Harber *et al.*, 1982). However, little data exist on the effects of an additional cover (i.e. SM) on the respiratory gas concentrations and pressures resulting from the respirator, and the effects of the shape of the additional cover on the characteristics of the FFR (Roberge, 2008). Other NIOSH research has indicated significant elevated inhaled CO_2 associated with various respirators. Sinkule *et al.* (2003) investigated five types of respiratory protection using the ABMS: air-purifying respirators (n = 27), air-supplied respirators (n = 20), gas masks (n = 6), powered air-purifying respirators (n = 11), and FFRs (n = 26). Using the same six levels of energy expenditure as the present investigation, FFRs (type was not stratified) produced the highest levels of average inhaled CO_2 concentrations and lowest average inhaled O_2 concentrations for all levels of energy expenditure as compared with all other respiratory protective devices examined. Table 3 contains average inhaled CO_2 concentrations among the FFRs used in the present investigation. The practical significance of these findings includes the influence of dead space upon the inhaled CO_2 concentrations among horizontal flat-fold FFRs, which were larger in comparison than the other types of FFRs without an SM.

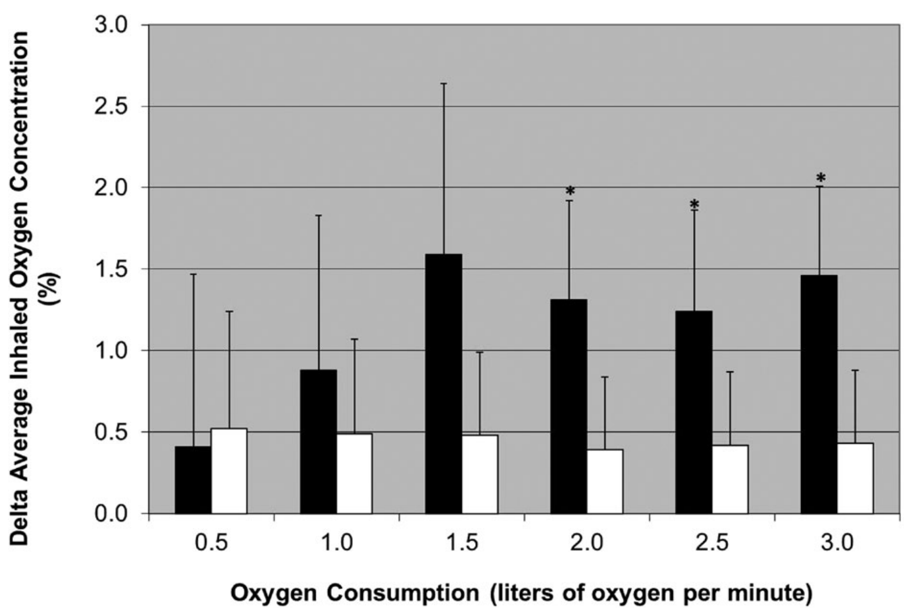

Fig. 2. Average inhaled O_2 delta (FFR with exhalation valve minus FFR without exhalation valve) concentrations (mean ± SD) in FFR with and without surgical mask covers for all levels of oxygen consumption. FFR without surgical mask covers (FFR only) = black bars, FFR with surgical mask covers (FFR+SM) = white bars. Significantly different from FFR+SM, $P < 0.05$.

There currently is no inhaled CO_2 concentration threshold value for NIOSH certification testing of FFRs. The average inhaled CO_2 concentrations were above the NIOSH Short-Term Exposure Limit of 0.5% among all levels of energy expenditure, without and with SM. The threshold for the NIOSH Ceiling of CO_2 is 3% by volume. The NIOSH Ceiling is used to describe occupational exposures that shall not be exceeded through any part of the workday (American Conference of Governmental Industrial Hygienists, 2008). Individually, three of the 30 FFR models tested without SM produced average inhaled CO_2 concentrations above 4%, which is Immediately Dangerous to Life and Health (IDLH). IDLH is the designation of maximal exposure above which only highly reliable respiratory protection provides maximal worker protection. One FFR model was withdrawn from the analysis based upon the exceptionally large average inhaled CO_2 concentration—5.8% at $\dot{V}O_2$ of 0.5 $l{\cdot}min^{-1}$. The performance of this FFR model was a true outlier that skewed analyses. Manufacturing of this FFR was discontinued during the course of this investigation and it is no longer commercially available. In addition to the discontinued FFRs, another FFR (without SM) produced average inhaled CO_2 concentrations above 5% at the energy expenditure of 1.5 $l{\cdot}min^{-1}$. Of the FFRs without SM, three horizontal flat-fold FFR models (one with an EV) produced average inhaled CO_2 concentrations between 4 and 5% at $\dot{V}O_2$ of 0.5 $l{\cdot}min^{-1}$, as well as one horizontal flat-fold FFR at $\dot{V}O_2$ of 1.0 $l{\cdot}min^{-1}$ and one cup FFR at $\dot{V}O_2$ of 1.5 $l{\cdot}min^{-1}$.

The respirator provides a micro-environment for the exposure pathway of inhaled CO_2 (Checkoway *et al.*, 2004; Nieuwenhuijsen, 2006). According to CFR 42 Part 84, the highest inhaled CO_2 concentration specified for respiratory protection is 2.5% for ≤30 min among the self-contained breathing apparatus (Approval of Respiratory Protection Devices, 2006). A standard test procedure used by NIOSH for the evaluation of negative-pressure air-purifying hooded respirators for escape only contains an inhaled CO_2 concentration threshold of 2.5% for apparatus of 15–30 min duration, and 2.0% for an apparatus of 45–60 min duration (National Institute for Occupational Safety and Health, 2006). Of the FFRs in this investigation, most average inhaled CO_2 concentrations were lower than 2.0% for levels of energy expenditure at 2.0 $l{\cdot}min^{-1}$ or greater, both without and with an SM. At levels of energy expenditure of 1.5 $l{\cdot}min^{-1}$ or lower, most average inhaled CO_2 concentrations appeared above 2.0% for all FFRs and more so at the lowest level of energy expenditure (rest). The recognizable effect of inhaled CO_2 is the stimulating action upon respiration, i.e. respiratory removal of CO_2 occurs through the increase in ventilation rate. Respiratory rate, tidal volume, and alveolar CO_2 become elevated with inhaled CO_2 concentrations above ambient (Schneider and Truesdale, 1922; Consolazio *et al.*, 1947; Patterson *et al.*, 1955). These physiological responses occur to compensate for abnormal diffusion of CO_2 from the blood, due to a decrease in the ratio of alveolar to capillary CO_2 (Schulte, 1964). In addition to the increased rate and depth of breathing, cardiac output will increase to compensate for the additional CO_2 (Schulte, 1964). While inhaling 1–2% CO_2 for 17–32 min, slight increases have been reported in systolic and diastolic blood pressures (Schneider and Truesdale, 1922). Exposures of increased inhaled CO_2 between 2 and 3% have been known to produce sweating, headache, and dyspnea for some subjects at rest after several hours (Schneider and Truesdale, 1922). If inhaled CO_2 concentrations are between 4 and 5%, dyspnea can occur within several minutes and increased blood pressure, dizziness, and headache can occur within 15–32 min (Schneider and Truesdale, 1922; Patterson *et al.*, 1955; Schulte, 1964). If inhaled CO_2 exposures are at 5%, mental depression may occur within several hours (Consolazio *et al.*, 1947; Schulte, 1964). As noted in several of these studies, headaches have been reported at inhaled CO_2 concentrations similar to those found in this investigation. This is consistent with one study which found that 37% of healthcare workers surveyed reported headaches following FFR use (Lim *et al.*, 2006).

A striking unanticipated finding among the horizontal flat-fold FFRs was a *reduction* in the average inhaled CO_2 concentration when an SM was applied as an additional layer of protection at $\dot{V}O_2$ of 1.0 and 1.5 $l{\cdot}min^{-1}$ (Table 3). The high average inhaled CO_2 concentrations among horizontal flat-fold FFRs without an SM were caused by the larger respirator dead space as compared with the cup type FFR or other flat-fold FFR models. The effective respirator dead space was increased by inflating the horizontal flat-fold FFRs during exhalation. The application of the horizontal flat-fold type of SM—a glove-to-hand sleeve over the horizontal flat-fold FFRs—restricted the inflation effect during exhalation and reduced the effect of an increased dead space. The average inhaled CO_2 concentration among cup FFRs increased among those with an SM as compared with those without the SM at $\dot{V}O_2$ of 0.5 $l{\cdot}min^{-1}$, 2.5 $l{\cdot}min^{-1}$ and 3.0 $l{\cdot}min^{-1}$, due to the additional dead space caused by the horizontal flat-fold type of SM. For the other flat-fold FFRs, three FFR models were of the tri-fold type and three FFR models were of the vertical flat-fold type. The orientation of these other flat-fold types on the user's face and other dead space features would affect the average inhaled CO_2 concentrations. With an SM, the orientation of the other flat-fold FFRs (vertical flat-fold and tri-fold) would change on the user's face. Placing a horizontal flat-fold SM on a vertical flat-fold FFR would require bending the corners/ends of the vertical flat-fold FFR, which probably would decrease the dead space within the FFR. Bending of the folds in tri-folded FFR would be needed with the application of a horizontally flat-folded SM, which also would reduce the dead space in the FFR. Any bending or folding of the FFR filter material also compromises the total surface area of the filter media and filtration efficiency. The variability of the average inhaled CO_2 concentration results among the various types of flat-fold FFR combined in the "other flat-fold" category contributed to insignificant differences between this type of FFR with and without SM because this category contained only six models between two types of FFR (vertical flat-fold and tri-fold).

The changes in average inhaled O_2 concentration closely followed the expected reciprocal displacement by average inhaled CO_2, whereas average inhaled O_2 concentration increased in conditions where average inhaled CO_2 concentration decreased and vice versa. One reason for the changes in average inhaled O_2 concentration relative to average inhaled CO_2 concentration is because of the relative displacement of the gases in air; the changes in one gas directly allows for a greater or lesser proportion of the other gases. Like the unanticipated change that occurred among the horizontal flat-fold FFRs, where a *reduction* in the average inhaled CO_2 concentration was observed when an SM was applied as an additional layer of protection at $\dot{V}O_2$ of 1.0 $l \cdot min^{-1}$ and 1.5 $l \cdot min^{-1}$, an *increase* in the average inhaled O_2 concentration also occurred for this select subset of FFRs. According to CFR 42 Part 84, a hazardous atmosphere includes any oxygen-deficient atmosphere of less than a partial pressure of 148 mmHg or 19.5% O_2 (Approval of Respiratory Protection Devices 2011). From Table 4, the average inhaled O_2 concentrations were below 19.5% for all conditions and all levels of energy expenditure, except for the condition of "N95 only" at the level of O_2 consumption of 2.5 $l \cdot min^{-1}$. The average inhaled O_2 concentration of ≤15% occurred in one FFR without SM during the 0.5 $l \cdot min^{-1}$ and 1.5 $l \cdot min^{-1}$ levels of energy expenditure. In a clinical trial, inhaled oxygen concentration of 15% caused more time needed to travel a standard distance with the lowest power output measured and coincided with the highest measured capillary blood lactate concentrations when compared with normoxia and hyperoxia (F_IO_2, 100%); caused the recruitment of specific muscle fiber types (reducing fatigue-resistant type I fibers and increasing type II fibers), muscle fatigue, reduced release of calcium ion from the sarcoplasmic reticulum, increased minute ventilation by 26%, and decrease O_2 consumption by 10% (Amann *et al.*, 2006). At the threshold partial pressure of O_2 at 132 mmHg (17.4% O_2), symptoms include headache, lightheadedness, drowsiness, muscular weakness, dyspnea on exertion, nausea, and vomiting (Schulte, 1964). Neurological symptoms, such as reduced memory, mental work capacity, auditory and visual disturbances, vertigo, tinnitus, and irritability, may be manifested if O_2 deficiency continues (Schulte, 1964).

Future research may consider human subject testing of various FFR models, adjusted for age and gender, while measuring volume-weighted mean inhaled CO_2 and O_2 gas concentrations and comparing the responses to average inhaled CO_2 and O_2 gas concentrations from the ABMS. This proposed research may provide a connection of ABMS results with human subject responses for use in the development of an ABMS-based standard test procedure for evaluating negative-pressure air-purifying respiratory protective devices. Certain special groups also may benefit from exploratory research using the ABMS to evaluate respiratory protection, e.g. children that use respiratory protection while performing activities in the agricultural industry.

Breathing pressures

The peak inhalation and exhalation pressures could impact respirator comfort, in addition to inhalation and exhalation temperatures, respirator weight, respirator valves, etc. The increased pressure may cause a decrease in respiratory rate (Harber *et al.*, 1982; Louhevaara, 1984) and tidal volume (Harber *et al.*, 1982). Among older individuals, respiratory rate may not change and tidal volume decreases with increased inspiratory resistance (Louhevaara, 1984). Tables 5 (Peak exhalation pressures) and 6 (Peak inhalation pressures) show how the breathing pressures increased with energy expenditure, where respiratory rate and tidal volume caused more air flow during inhalation and exhalation. During exhalation, the differences between FFRs with and without SM occur only in cup type of FFRs. The difference in the group with the largest representation (cup type with 60% of the sample) would explain the variation. In a previous NIOSH investigation of FFR breathing pressures with and without SM using a breathing machine, mean FFR alone and without EVs (three models) at minute ventilations of 25 $l \cdot min^{-1}$

and 40 l·min^{-1} with a sinusoidal breathing waveform reported exhalation pressures of 7 mmH_2O and 11 mmH_2O, respectively (Vojtko *et al.*, 2008). From the same report, the mean FFR with an SM at minute ventilations of 25 l·min^{-1} and 40 l·min^{-1} and sinusoidal breathing waveform reported mean exhalation pressures of 8 mmH_2O and 12 mmH_2O, respectively. In FFR with EV (one model), Vojtko reported 4 mmH_2O and 5 mmH_2O, respectively, at 25 l·min^{-1} and 40 l·min^{-1} for FFR alone; and, 4 mmH_2O and 6 mmH_2O, respectively, for FFRs with SM. The most significant factors contributing to the differences between the data reported from this study and the Vojtko study could be due to a larger sample size (30 FFR models versus 4 FFR models) and the difference in the minute ventilation values expressed by the Vojtko study (atmospheric temperature and pressure (ATP), ambient) and the present study (body temperature (37°C), ambient pressure, and saturated with water vapor (BTPS)). The conversion from ATP to BTPS (used from the ABMS) would change minute ventilation from 25 l·min^{-1} to 27 l·min^{-1} and from 40 l·min^{-1} to 44 l·min^{-1} (Cotes *et al.*, 2006). Thus, the BTPS-adjusted minute ventilations from the manikin data used in the Vojtko *et al.* (2008) study are lower than the similar minute ventilations of the ABMS, 30.6 l·min^{-1} and 45.6 l·min^{-1}, respectively (Table 2).

The comparisons of pressures between FFRs that were paired models with and without EVs were of significant importance. First, the differences (deltas) in average inhaled CO_2 (Figure 1) and O_2 (Figure 2) between FFRs with EVs (FFR+EV) and FFRs without EVs (FFR−EV) were largest at the middle and high levels of energy expenditure, indicating the EVs were remaining closed at the lowest levels of energy expenditure. With the SM, the delta values in average inhaled CO_2 (Figure 1) and O_2 (Figure 2) between FFR+EV and FFR−EV were consistently low among all levels of energy expenditure, suggesting that the insufficient pressure difference between the inside of the FFR and the intra-mask space of the FFR and SM prevented the opening of the EVs. Others have reported no differences in heart rate, breathing rate, tidal volume, minute volume, transcutaneous carbon dioxide, and oxygen saturation from human participants wearing FFR+EV and FFR−EV, with and without SM, at $\dot{V}O_2$ between 0.6 l·min^{-1} and 0.8 l·min^{-1} which also suggest the pressure differences between the inside and outside of the FFRs were insufficient to open the EVs both with and without SM (Roberge *et al.*, 2010).

Second, the exhaled and inhaled pressure results for the paired FFRs were similar to the overall group results, except at $\dot{V}O_2$ = 1.5 l·min^{-1} where the significant effect ($P < 0.05$) of SM use with an EV was not present among the paired FFRs and a significant effect of SM use occurred only among the paired FFRs. The homogeneous characteristics of the paired FFRs would limit variability of various cup depths on the user's face. When homogeneous sizes were procured for this investigation, the majority of the sizes (77%) were universal, or one-size-fits-all. Size specifications for FFRs are determined by manufacturers. The medium size, or universal size, for one manufacturer may not be equivalent to that of another manufacturer. Furthermore, FFR sizes may not be equivalent among various models from the same manufacturer.

The various universal/medium-sized FFRs were positioned on the ABMS head form by the same person for all tests. Landmarks on the head form (for example, eye, nose, chin locations) were used to position the FFR and SM, per the manufacturer's instructions. Although uniformity of FFR positioning was maintained, the various depths and the various types of FFRs positioned on the same head form produced variations in dead space from the FFRs.

Clinically, it would be important to know when humans find the added pressure from FFRs wear intolerable or the point where users detect the added pressure from an SM. Two reports investigated the minimal pressures that can be detected in humans from elastic and non-elastic loads (Campbell *et al.*, 1961; Bennett *et al.*, 1962). Bennett *et al.* (1962) conducted a study using added restrictive loads to measure the ability to determine the lowest restriction noticeable by humans. Participants were asked to breathe (assuming inhalation and exhalation were weighted equally) through progressively narrowed calibrated tubes (between 2 $mmH_2O·l^{-1}·s^{-1}$ and 12 $mmH_2O·l^{-1}·s^{-1}$). The mean 50% level of detection was 6 $mmH_2O·l^{-1}·s^{-1}$ (BTPS). Bennett reported a non-linear relationship between the pressure and flow characteristics for each load. The relationship between the results from Bennett *et al.* (1962) and the ranges of pressures in Table 8, the mean exhalation pressures (Table 5), and the mean inhalation pressures (Table 6), can be used to estimate the level of energy expenditure where an SM addition to using an FFR is detected by humans. During exhalation (Table 5), the difference in pressures at the energy expenditure commensurate with the flow rate in the Bennett study (at $\dot{V}O_2$ between 0.5 l·min^{-1} and 1.0 l·min^{-1} by the ABMS) between FFRs and FFR+SM were smaller than the 50% level of detection for each flow. The same comparison analysis among the FFRs and FFR+SM during inhalation (Table 6) also demonstrate that the difference in pressures were smaller than the 50%

level of detection for the flow at $\dot{V}O_2$ between 0.5 $l \cdot min^{-1}$ and 1.0 $l \cdot min^{-1}$. These results suggest that the increased pressures resulting from the addition of the SM at the lower levels of energy expenditure used in this investigation would not be detected in humans as compared with using the same FFR without an SM. These are the same levels of energy expenditure that occur with a significant portion of activities conducted by healthcare workers.

STUDY LIMITATIONS

Although the ABMS is an accurate, reproducible, functional, and useful tool to characterize the metabolic responses that can be produced by the use of respiratory protection, there are limitations to its use. For negative pressure respiratory protection, such as FFRs, elastomeric air-purifying respirators, and gas masks, the ABMS measurements for the respirator's dead space are affected primarily by the minute ventilation, more specifically, tidal volume. As the normal user's tidal volume decreases, the effect from respirator dead space becomes greater. Conversely, the opposite occurs as tidal volume increases, such as that in normal larger persons and exercise. In a field study, smaller healthcare workers (e.g. women) were more probable to experience intolerance for wearing FFRs before the end of the shift (Radonovich *et al.*, 2009). The limitation, therefore, is characterizing respiratory protection with a tidal volume specific to the human data used to program the metabolic parameters of the ABMS, or a subset of subjects with a body size of 85–92 kg.

Another limitation for the ABMS is that it does not respond, that is, respiratory protection for the ABMS does not cause changes in breathing times, breathing volumes/depths, or breathing rhythmicity. Humans respond to the changes in the breathing zone from the use of respiratory protection. However, those stimuli produced by the results of using respiratory protection are masked by the human response. The human response was similar to the ABMS measurements in a previous investigation (Sinkule and Turner, 2004). The stimuli from using various forms of respiratory protection, or types of FFRs and treatments affecting FFRs (e.g. SM), will vary in magnitude. These effects were characterized in this investigation. Some human participants are hyposensitive to CO_2 and metabolic acidosis, and do not respond normally to increased CO_2 concentrations until hyperventilation occurs at exhaustive workloads (Whipp *et al.*, 1989).

CONCLUSIONS

Approximately 10% of commercially available NIOSH-approved FFR models were examined with and without SM using the ABMS to characterize metabolic responses in an attempt to understand the implications of the recommendation to apply an SM over the FFR to extend the respirator's useful life for healthcare workers. Conclusions for this investigation include the following:

1. generally, average inhaled CO_2 decreased and average inhaled O_2 increased with increasing oxygen consumption in FFRs and FFRs with SM;
2. peak exhalation pressure and peak inhalation pressure increased with increasing oxygen consumption, but more so in FFRs with SM;
3. as compared with FFRs without SM, higher average inhaled CO_2 were observed in four of six workloads among FFRs with SM;
4. the addition of the SM to horizontal flat-fold FFRs at $\dot{V}O_2$ of 1.0 $l \cdot min^{-1}$ and 1.5 $l \cdot min^{-1}$ caused a *reduction* in average inhaled CO_2 and an *increase* in average inhaled O_2 due to the effects of the (horizontal flat-fold) SM on the FFR dead space;

Table 8. Representative peak flow and peak pressure ranges at each level of energy expenditure (n = 30).

Oxygen consumption, ($l \cdot min^{-1}$, STPD)	Approx. peak flow ($l \cdot min^{-1}$, BTPS)	Peak exhalation pressure range for (mmH_2O)		Peak inhalation pressure range for (mmH_2O)	
		FFR only	FFR + SM	FR only	FFR + SM
0.5	45.0	3–12	4–14	−2 to −8	−4 to −10
1.0	96.6	6–15	7–17	−8 to −19	−14 to −23
1.5	149.5	8–23	10–26	−13 to −31	−14 to −37
2.0	243.8	13–40	18–45	−25 to −55	−26 to −68
2.5	209.3 exhaled; 241.5 inhaled	11–34	16–38	−25 to −55	−26 to −68
3.0	246.1 exhaled; 276.0 inhaled	13–41	18–45	−30 to −67	−31 to −90

5. within matched models of FFRs with and without EVs (without SM), the delta average inhaled CO_2 and inhaled O_2 concentrations were lowest at $\dot{V}O_2$ = 0.5 l·min^{-1} where the lowest flows appeared insufficient for opening the EVs; and,
6. FFRs (matched models with and without EVs) with an SM produced small and similar delta average inhaled CO_2 and O_2 concentrations across the spectrum of energy expenditures suggesting an insufficient pressure differential between the inside of the FFR and the space between the FFRs and SM, which prevented the EVs from opening.

At the lower levels of energy expenditure, this investigation provided evidence to suggest that the IOM recommendation of adding an SM over FFRs in order to extend the daily duration of FFRs and reduce the consumption of FFRs during a pandemic would produce clinically small changes in inhaled breathing gases and breathing pressures resulting in a minimal effect on physical work performance, and the amount and direction of change is affected by the type of FFR and shape of the SM. In addition, the evidence also indicates possible improvements in inhaled breathing gases caused by the effects in the dead space characteristics of the FFRs by the shape of the SM. If the FFR is equipped with EVs, the evidence suggests that the SM prevents the opening of the EVs because of the pressure change in the space between the FFRs and the SM. The ability of the SM to change the pressure characteristics in the space between the FFRs and SM occurred across the spectrum of energy expenditures.

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