Physiological Impact of the N95 Filtering Facepiece Respirator on Healthcare Workers

Raymond J Roberge MD MPH, Aitor Coca PhD, W Jon Williams PhD, Jeffrey B Powell MSc, and Andrew J Palmiero

OBJECTIVE: To assess the physiological impact of the N95 filtering facepiece respirator (FFR) on healthcare workers. METHODS: Ten healthcare workers each conducted multiple 1-hour treadmill walking sessions, at 1.7 miles/h, and at 2.5 miles/h, while wearing FFR with exhalation valve, FFR without exhalation valve, and without FFR (control session). We monitored heart rate, respiratory rate, tidal volume, minute volume, blood oxygen saturation, and transcutaneously measured P_{CO_2}. We also measured user comfort and exertion, FFR moisture retention, and the carbon dioxide and oxygen concentrations in the FFR's dead space. RESULTS: There were no significant differences between FFR and control in the physiological variables, exertion scores, or comfort scores. There was no significant difference in moisture retention between FFR with and without exhalation valve. Two subjects had peak $P_{CO_2} \geq 50$ mm Hg. The FFR with exhalation valve offered no benefit in physiological burden over the FFR without valve. The FFR dead-space oxygen and carbon dioxide levels did not meet the Occupational Safety and Health Administration's ambient workplace standards. CONCLUSIONS: In healthy healthcare workers, FFR did not impose any important physiological burden during 1 hour of use, at realistic clinical work rates, but the FFR dead-space carbon dioxide and oxygen levels were significantly above and below, respectively, the ambient workplace standards, and elevated P_{CO_2} is a possibility. Exhalation valve did not significantly ameliorate the FFR's P_{CO_2} impact. *Key words: N95 filtering facepiece; respirator; physiological;* healthcare workers*; comfort; exertion; Occupational Safety and Health Administration; workplace*. [Respir Care 2010;55(5):569–577]

Introduction

Concerns over emerging airborne infectious diseases have highlighted the importance of respiratory protection for healthcare workers.[1] Respiratory protection in healthcare settings is generally accomplished by engineering and administrative controls and the use of respiratory protective equipment such as filtering facepiece respirators (FFRs), of which the most commonly recommended and used are N95 FFRs[2] (frequently incorrectly referred to as N95 masks). Despite widespread use, few published data exist regarding the physiological impact of FFRs on healthcare workers. We assessed the physiological impact upon healthcare workers of an N95 FFR with and without an exhalation valve, and measured the oxygen and carbon dioxide levels in the FFR's dead space (FFR V_D).

Raymond J Roberge MD MPH, Aitor Coca PhD, W Jon Williams PhD, Jeffrey B Powell MSc, and Andrew J Palmiero are affiliated with the Technology Research Branch, National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Pittsburgh, Pennsylvania.

The authors have disclosed no conflicts of interest.

The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health.

Correspondence: Raymond J Roberge MD MPH, Technology Research Branch, National Personal Protective Technology Laboratory, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 626 Cochrans Mill Road, Pittsburgh PA 15236. E-mail: dtn0@cdc.gov.

Methods

Subjects

We recruited 10 healthy healthcare workers (7 women, 3 men, ages 20–45 y) who were experienced with wearing FFR (Table 1). Exclusion criteria included pregnancy, smoking, cardiopulmonary disorder, musculoskeletal disorder that prevented exercise, and inability to be adequately fit-tested

Table 1. Subject Demographics

Subject	Professional Category	Age (y)	Weight (kg)	Height (cm)	Body Mass Index (kg/m^2)	Sex
1	Nurse	42	75.3	155	31.3	Female
2	Nurse	22	47.6	165	17.4	Female
3	Physical therapy technician	24	64.5	162	24.4	Female
4	Physical therapy technician	23	126.4	162	47.7	Female
5	Patient-care assistant	20	105.4	183	31.5	Male
6	Patient-care assistant	34	55.4	157	22.3	Female
7	Patient-care assistant	20	68.8	188	19.4	Male
9	Nursing student	21	56.8	165	20.8	Female
9	Nursing student	22	69.5	170	23.9	Female
10	Physical therapy student	23	85.8	183	25.5	Male
Mean		25	76.0	169	26.4	

with the FFR. Nine of the subjects had never smoked, and one had not smoked in $>$ 1 y (20 pack-year history). The study was approved by the National Institute for Occupational Safety and Health (NIOSH) human subjects review board, and all subjects provided oral and written informed consent.

Physiological Monitoring Equipment

We used the LifeShirt System (VivoMetrics, Ventura, California), a lightweight spandex vest that incorporates physiological sensors and circumferential respiratory-inductive-plethysmography bands, to monitor heart rate, respiratory rate, and tidal volume (V_T). We calculated minute volume ($\dot{V}_E$) as the product of respiratory rate and V_T. We calibrated the LifeShirt against a fixed volume before each use.

Timed CO_2 and O_2 averages were obtained via a gas analyzer (CO_2 sensor model p61-B, O_2 analyzer model S3-A/I, AEI Technologies, Naperville, Illinois) that continuously sampled the FFR V_D gas at 18 samples/s (total sampling volume 500 mL/min) via a 2-mm inner-diameter sampling line attached to a port in the FFR that was equidistant between the nares and mouth. The gas analyzer was calibrated daily with a protocol that uses standards traceable to the National Institute of Standards and Technology.

We continuously transcutaneously measured CO_2 (P_{tcCO_2}) and O_2 saturation (S_{pO_2}) (Tosca 500 monitor, Radiometer, Copenhagen, Denmark, which uses a heated, earlobe-mounted, combination pulse oximeter and Severinghaus-type heated sensor that potentiometrically measures the partial pressure of CO_2 by determining the pH of an electrolyte layer separated from the skin by a highly permeable membrane: a pH change is proportional to the logarithm of P_{CO_2} change).[3] We calibrated the unit over a 10-min period prior to each use.

Filtering Facepiece Respirator Model Selection

The 2 N95 FFR models (from 2 manufacturers) we studied are representative of supplies in the National Strategic Stockpile, which is a federal-government-maintained repository of medical supplies likely to be the first distributed to healthcare workers in a large-scale medical emergency.[4] The National Strategic Stockpile does not include FFRs with exhalation valves, so we chose 2 exhalation-valved FFRs that were similar in shape and size to the National Strategic Stockpile FFRs, and made by the same manufacturers. All the FFRs we tested were cup-shaped, and we used a new FFR for each study session. We weighed each FFR before and after the session to measure moisture retention.

Filtering Facepiece Respirator Fit Testing

To determine the FFR size that provided the best seal on the face, we quantitatively evaluated FFR fit. We quantified fit factor (ratio of ambient-air particle concentration to inside-the-FFR particle concentration) with a respirator-fit test device (PortaCount Plus, TSI, Shoreview, Minnesota), which measures optical density with condensation-nucleus-counting technology, to calculate leakage into the FFR while the subject performed a series of 8 exercises.[5] We fit tested the subjects with each FFR and FFR-with-valve model, and all subjects attained an overall fit factor of $\geq$ 100, which indicates leakage of $\leq$ 1%, the level required by the Occupational Safety and Health Administration.[5,6] Eight subjects passed fit testing with the medium/large (ie, standard) FFR, and 2 subjects required the small FFR.

Test Procedures

Control Studies. Subjects donned the LifeShirt, and were tested in athletic shorts, tee-shirt and athletic shoes. The Tosca 500 sensor was attached to the left earlobe, and we

obtained control physiologic data for each subject continuously over 15 min at 2 treadmill speeds that represent realistic healthcare worker activity levels and that have been used in other FFR studies[7-9]: treadmill speed 1.7 miles/h, incline 0°, which equates to stationary work (eg, writing nursing notes, answering phones); and treadmill speed 2.5 miles/h, incline 0°, which equates to bedside nursing patient-care activities. The control 15-min exercise interval was selected because, at relatively low-intensity steady-state exercise, steady-state respiratory variables are achieved in 3–6 min in healthy subjects.[10,11] The treadmill was calibrated prior to the study.

Filtering Facepiece Respirator Studies. Subjects were clothed and instrumented as in the control studies, donned, in randomly-assigned order, and according to the manufacturer's instructions, the FFR or FFR-with-valve, performed positive and negative face-seal checks (with the gas-sampling line pinched off), and treadmill-walked for 1 hour (mean nurse FFR wear time per shift[12]), in the randomly-assigned order for work rate, while physiological variables were continuously monitored. Every 5 min we queried the subjects with the modified Borg Perceived Exertion Scale[13] and the modified Perceived Comfort Scale.[14] Talking was permitted ad lib during the testing, to mimic healthcare workers communicating while wearing the FFR. Upon completing the exercise session, the subjects filled out questionnaires relating to complaints commonly referable to FFR use (eg, heat, sweating, itching, and lightheadedness) and were allowed to add personal comments related to any subjective sensations they experienced or FFR design features that caused discomfort. The study sessions were generally limited to 2 per day, with a minimum 30-min break between the sessions. Each subject conducted 4 exercise sessions (one with each FFR and FFR-with-valve) and one control session at each work rate. The study laboratory temperature was maintained at 22°C, and relative humidity averaged 54% (range 39–70%).

Statistical Analysis

We used statistics software (SPSS 16.0, SPSS, Chicago, Illinois) for the statistical analyses. We report the physiological data and FFR V_D CO_2 and O_2 data as mean ± SD. The sessions were 1 hour, and the data variables are summarized at 1, 15, 30, 45, and 60 min. We performed 2 × 2 × 5 (FFR type × work rate × time) analysis of variance (ANOVA) to assess the differences between FFR and FFR-with-valve at the 2 exercise intensities. To determine differences in the physiological variables, we performed 2 × 2 × 5 (FFR type × work rate × time) repeated-measures ANOVA for S_{pO_2}, P_{tcCO_2}, respiratory rate, V_T, $\dot{V}_E$, and heart rate, using the values from the control session (no FFR) as a covariate. We performed 2 × 2 × 5 (FFR type × work rate × time) repeated-measures ANOVA to examine the FFR V_D O_2 and CO_2 responses to the FFR and FFR-with-valve at the 2 exercise intensities. We further analyzed significant interactions with 1-way ANOVA and paired *t* tests with Bonferroni corrections, with the alpha level set at $P < .05$. We analyzed the exertion scores, comfort scores, and FFR weights with paired *t* tests. The null hypothesis was that there would be no significant differences ($P < .05$) in the studied physiological variables between the controls (no respirator) and the FFR and FFR-with-valve.

Results

Physiological Variables

There were no significant differences in the physiological variables at either work rate over 1 hour, when comparing controls to all FFR models. Similarly, when comparing FFR to FFR-with-valve, only respiratory rate was significantly lower with FFR, at the 1.7 miles/h work rate ($P = .02$). Between FFR and FFR-with-valve there were no significant differences in FFR V_D mean mixed inhalation/exhalation O_2 (16.6% vs 16.7%, $P = .30$) or CO_2 (2.9% vs 2.9%, $P = .47$), at both work rates (see Tables 2–7). Over 1 hour, the moisture retention in the FFR and the FFR-with-valve was 0.11 ± 0.15 g and 0.13 ± 0.09 g, respectively ($P = .46$). Tables 8–10 show the comfort scores, exertion scores, and subjective complaints.

Discussion

The protection afforded by respiratory protective equipment is partly counterbalanced by the physiological and psychological burden the equipment imposes on the user.[15] The current study found no significant differences in heart rate, respiratory rate, V_T, $\dot{V}_E$, S_{pO_2}, or P_{tcCO_2} between control and FFR or FFR-with-valve while exercising over 1 hour at realistic work rates.

The impact of FFR on ventilatory variables was modest. This was manifested as nonsignificant increases in V_T (range 38–148 mL), with concomitant nonsignificant, mild decrements in respiratory rate at both work rates over 1 hour (see Tables 3–7). This quantifies the mild added effort required to overcome the filter-media resistance of the relatively low-resistance FFRs we used (the NIOSH maximum certification initial exhalation and inhalation resistances are 35 mm H_2O and 25 mm H_2O column height pressure, respectively[5]) and the FFR V_D effects at the study work rates.[2,16]

Our finding of no significant difference in respiratory rate between control and FFR or FFR-with-valve is at variance with a previous investigation that included 8 healthcare workers and 2 industrial workers who treadmill exercised with an FFR, in whom there were statistically significant increases in respiratory rate at rest and during 5-min exercise periods with mild, moderate, and heavy work rates.[16] Unfortunately, $\dot{V}_E$ was not measured in that study,[16] and other study differences included FFR

Table 2. *P* Values for Differences in Physiological Variables: Control Versus Filtering Facepiece Respirator

	P Value for Difference Between After One Hour					
	Respiratory Rate	Heart Rate	Tidal Volume	Minute Volume	S_{pO_2}	P_{tcCO_2}
Control vs FFR						
At 1.7 miles/h	.48	.21	.59	.44	.95	.72
At 2.5 miles/h	.12	.15	.52	.30	.95	.57
FFR With vs Without Exhalation Valve						
At 1.7 miles/h	.02	.32	.61	.92	.54	.71
At 2.5 miles/h	.37	.47	.12	.07	.71	.55

FFR = filtering facepiece respirator
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide

Table 3. Physiological Variables After 1 Min of Filtering Facepiece Respirator

	At Treadmill Speed 1.7 miles/h			At Treadmill Speed 2.5 miles/h		
	Control*	FFR With Valve	FFR Without Valve	Control	FFR With Valve	FFR Without Valve
FFR Dead-Space Gases						
O_2 (%)	NA	17.2 ± 0.4	17.0 ± 0.5	NA	17.2 ± 1.0	17.0 ± 0.8
CO_2 (%)	NA	3.0 ± 0.4	3.0 ± 0.2	NA	3.1 ± 0.4	3.0 ± 0.5
S_{pO_2} (%)	98.5 ± 0.8	98.4 ± 0.5	98.1 ± 0.9	98.5 ± 0.8	98.1 ± 1.2	98.1 ± 0.9
P_{tcCO_2} (mm Hg)	40.7 ± 3.5	40.1 ± 2.7	39.9 ± 2.8	40.8 ± 3.2	39.7 ± 2.6	40.8 ± 2.9
f (breaths/min)	27.7 ± 7.1	25.2 ± 6.9	21.7 ± 6.3	27.7 ± 8.6	22.4 ± 7.0	23.9 ± 9.0
V_T (mL)	793 ± 215	944 ± 297	932 ± 253	864 ± 205	937 ± 277	1,013 ± 309
$\dot{V}_E$ (L/min)	20.9 ± 8.2	22.4 ± 4.6	19.6 ± 6.1	23.0 ± 6.5	20.4 ± 6.3	23.0 ± 7.2
Heart rate (beats/min)	92.3 ± 8.2	92.8 ± 11.2	94.8 ± 10.3	101.3 ± 11.8	98.7 ± 11.0	101.3 ± 9.4

* Control test was 15 min of physiological monitoring while not wearing a filtering facepiece respirator (FFR).
NA = not applicable
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide
f = frequency (respiratory rate)
V_T = tidal volume
$\dot{V}_E$ = minute ventilation

features (eg, absence of exhalation valve), dissimilar work intensities and exercise duration, and different respiratory-rate measurement techniques and measurement times. FFR use during a sedentary activity (ie, 4 h of hemodialysis) increased respiratory rate by only 2 breaths/min.[17] In the current study we found a significantly higher respiratory rate with the FFR-with-valve than with the FFR without valve at 1.7 miles/h (see Table 2). That finding is somewhat counterintuitive, given that the exhalation valve is designed to diminish exhalation resistance and, thus, the work of breathing. However, the exhalation valve's function depends on breathing-resistance-related development of streamline air flows that allow egress of exhaled gas through the valve, and these air flows may not be generated at a lower work rate in a low-resistance FFR-with-valve.[18] We observed no grossly visible exhalation-valve movement during multiple random checks, though it is possible that subtle valve movements occurred.

In terms of cardiac impact, the nonsignificant difference in heart rate between control and FFR and FFR-with-valve in the current study is congruent with other studies up to 1 hour of FFR use.[8,16,19] One study reported a mild decrease in heart rate with FFR during 4 hours of sedentary activity.[17] FFR-associated increased heart rate relates to breathing resistance, work level, physical fitness, FFR-associated anxiety, and increased retention of CO_2.[16,20] The present study's low work rates, the subjects' prior FFR experience, associated normal P_{tcCO_2} levels, and our use of low-resistance FFRs underscore why heart rate was not significantly higher than control.

The similar S_{pO_2} values between the controls and all the FFR models in the current study mirror a previous report

Table 4. Physiological Variables After 15 Min of Filtering Facepiece Respirator

	At Treadmill Speed 1.7 miles/h			At Treadmill Speed 2.5 miles/h		
	Control*	FFR With Valve	FFR Without Valve	Control	FFR With Valve	FFR Without Valve
FFR Dead-Space Gases						
O_2 (%)	NA	17.4 ± 0.6	17.3 ± 0.4	NA	17.6 ± 0.9	17.3 ± 0.7
CO_2 (%)	NA	3.0 ± 0.3	3.1 ± 0.2	NA	3.0 ± 0.3	3.2 ± 0.5
S_{pO_2} (%)	98.5 ± 0.8	98.3 ± 0.7	98.3 ± 0.8	98.5 ± 0.8	98.5 ± 0.8	98.0 ± 0.7
P_{tcCO_2} (mm Hg)	40.7 ± 3.5	41.9 ± 3.7	40.3 ± 4.2	40.8 ± 3.2	43.1 ± 5.0	42.6 ± 4.8
f (breaths/min)	27.7 ± 7.1	24.7 ± 6.6	23.8 ± 4.8	27.7 ± 8.6	25.4 ± 6.3	25.5 ± 9.0
V_T (mL)	793 ± 215	967 ± 328	972 ± 321	864 ± 205	938 ± 337	1,027 ± 302
$\dot{V}_E$ (L/min)	20.9 ± 8.2	22.8 ± 5.6	22.2 ± 4.5	23.0 ± 6.5	23.0 ± 7.4	25.0 ± 7.4
Heart rate (beats/min)	92.3 ± 8.2	96.6 ± 10.6	97.9 ± 8.3	101.3 ± 11.8	103.5 ± 9.1	105.9 ± 9.6

* Control test was 15 min of physiological monitoring while not wearing a filtering facepiece respirator (FFR).
NA = not applicable
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide
f = frequency (respiratory rate)
V_T = tidal volume
$\dot{V}_E$ = minute ventilation

Table 5. Physiological Variables After 30 Min of Filtering Facepiece Respirator

	At Treadmill Speed 1.7 miles/h			At Treadmill Speed 2.5 miles/h		
	Control*	FFR With Valve	FFR Without Valve	Control	FFR With Valve	FFR Without Valve
FFR Dead-Space Gases						
O_2 (%)	NA	17.3 ± 0.6	17.3 ± 0.4	NA	17.6 ± 0.9	17.3 ± 0.7
CO_2 (%)	NA	3.1 ± 0.3	3.0 ± 0.2	NA	3.0 ± 0.5	3.1 ± 0.5
S_{pO_2} (%)	98.5 ± 0.8	98.4 ± 0.8	98.3 ± 0.7	98.5 ± 0.8	98.6 ± 1.2	98.0 ± 0.9
P_{tcCO_2} (mm Hg)	40.7 ± 3.5	41.3 ± 4.2	40.3 ± 5.2	40.8 ± 3.2	42.4 ± 5.1	42.1 ± 4.7
f (breaths/min)	27.7 ± 7.1	25.4 ± 6.3	24.1 ± 5.0	27.7 ± 8.6	25.6 ± 5.9	26.7 ± 9.0
V_T (mL)	793 ± 215	915 ± 282	942 ± 339	864 ± 205	972 ± 339	1,001 ± 308
$\dot{V}_E$ (L/min)	20.9 ± 8.2	22.1 ± 4.3	22.0 ± 6.3	23.0 ± 6.5	24.0 ± 6.9	25.4 ± 7.0
Heart rate (beats/min)	92.3 ± 8.2	94.9 ± 10.5	99.9 ± 8.8	101.3 ± 11.8	103.9 ± 9.7	105.7 ± 8.9

* Control test was 15 min of physiological monitoring while not wearing a filtering facepiece respirator (FFR).
NA = not applicable
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide
f = frequency (respiratory rate)
V_T = tidal volume
$\dot{V}_E$ = minute ventilation

of a $< 1\%$ difference between controls and subjects wearing N95 FFRs during qualitative respirator-fit testing.[19] A recent study of the impact of a surgical mask on S_{pO_2} in surgeons during surgery found significant S_{pO_2} decreases only during procedures longer than 60 min.[21]

Kao et al[17] found a net P_{aO_2} decline of 9 ± 18.5 mm Hg from baseline in approximately 70% of 39 patients wearing N95 FFR after 4 hours of hemodialysis.

That limited prior experience[19,21] and the current study data suggest that S_{pO_2} decrements are possible with N95 FFR or N95 FFR-with-valve, but are likely to be minor for FFR use of ≤ 1 hour during low energy expenditure, and may not be clinically important.

Compared to control, P_{tcCO_2} did not differ significantly by work rate or FFR model. There were modest absolute increases in mean P_{tcCO_2} over 1 hour, compared to baseline, with the FFR-with-valve at 1.7 miles/h (P_{tcCO_2} 0.5 mm Hg higher) and 2.5 miles/h (P_{tcCO_2} 1.3 mm Hg higher), and with FFR at 2.5 miles/h (P_{tcCO_2} 1.2 mm Hg higher). These values are similar to those in a study that reported an average P_{aCO_2} of 1 ± 4.1 mm Hg after 4 hours of N95 FFR use during sedentary activity.[17] At 1.7 miles/h, the mean P_{tcCO_2} with FFR was modestly lower than control (−0.7 mm Hg). The lack of (expected) lower P_{tcCO_2} with the FFR-with-valve suggests that the exhalation valve may not decrease CO_2 at a low work rate, possibly because the

Table 6. Physiological Variables After 45 Min of Filtering Facepiece Respirator

	At Treadmill Speed 1.7 miles/h			At Treadmill Speed 2.5 miles/h		
	Control*	FFR With Valve	FFR Without Valve	Control	FFR With Valve	FFR Without Valve
FFR Dead-Space Gases						
O_2 (%)	NA	16.8 ± 0.7	16.8 ± 0.8	NA	17.3 ± 1.1	16.9 ± 0.4
CO_2 (%)	NA	2.9 ± 0.3	3.0 ± 0.3	NA	3.0 ± 0.4	3.0 ± 0.4
S_{pO_2} (%)	98.5 ± 0.8	98.2 ± 1.1	98.2 ± 0.9	98.5 ± 0.8	97.9 ± 1.1	98.4 ± 1.1
P_{tcCO_2} (mm Hg)	40.7 ± 3.5	41.4 ± 4.1	39.7 ± 5.2	40.8 ± 3.2	42.5 ± 5.5	42.6 ± 5.7
f (breaths/min)	27.7 ± 7.1	24.8 ± 7.2	25.7 ± 5.1	27.7 ± 8.6	25.5 ± 6.0	26.6 ± 9.7
V_T (mL)	793 ± 215	915 ± 314	948 ± 343	864 ± 205	962 ± 318	994 ± 313
$\dot{V}_E$ (L/min)	20.9 ± 8.2	21.5 ± 4.9	23.5 ± 6.8	23.0 ± 6.5	23.9 ± 7.2	25.0 ± 7.4
Heart rate (beats/min)	92.3 ± 8.2	95.6 ± 8.8	98.5 ± 8.0	101.3 ± 11.8	107.3 ± 8.7	107.4 ± 9.7

* Control test was 15 min of physiological monitoring while not wearing a filtering facepiece respirator (FFR).
NA = not applicable
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide
f = frequency (respiratory rate)
V_T = tidal volume
$\dot{V}_E$ = minute ventilation

Table 7. Physiological Variables After 60 Min of Filtering Facepiece Respirator

	At Treadmill Speed 1.7 miles/h			At Treadmill Speed 2.5 miles/h		
	Control*	FFR With Valve	FFR Without Valve	Control	FFR With Valve	FFR Without Valve
FFR Dead-Space Gases						
O_2 (%)	NA	16.5 ± 0.6	16.6 ± 0.6	NA	17.2 ± 1.1	16.6 ± 0.6
CO_2 (%)	NA	2.9 ± 0.4	2.9 ± 0.2	NA	3.0 ± 0.5	2.8 ± 0.4
S_{pO_2} (%)	98.5 ± 0.8	98.4 ± 1.0	98.1 ± 0.9	98.5 ± 0.8	98.2 ± 1.0	98.4 ± 0.7
P_{tcCO_2} (mm Hg)	40.7 ± 3.5	41.5 ± 4.9	39.7 ± 6.0	40.8 ± 3.2	42.6 ± 6.2	42.0 ± 5.6
f (breaths/min)	27.7 ± 7.1	25.2 ± 6.1	25.2 ± 4.0	27.7 ± 8.6	25.5 ± 5.7	26.6 ± 6.8
V_T (mL)	793 ± 215	878 ± 253	950 ± 358	864 ± 205	932 ± 297	945 ± 241
$\dot{V}_E$ (L/min)	20.9 ± 8.2	21.2 ± 4.5	23.4 ± 6.7	23.0 ± 6.5	23.0 ± 5.9	24.4 ± 6.0
Heart rate (beats/min)	92.3 ± 8.2	95.1 ± 9.7	98.1 ± 8.5	101.3 ± 11.8	106.4 ± 9.3	106.4 ± 9.2

* Control test was 15 min of physiological monitoring while not wearing a filtering facepiece respirator (FFR).
NA = not applicable
S_{PO_2} = blood oxygen saturation measured via pulse oximetry
P_{tcCO_2} = transcutaneously measured partial pressure of carbon dioxide
f = frequency (respiratory rate)
V_T = tidal volume
$\dot{V}_E$ = minute ventilation

exhalation pressure is not sufficient to activate the exhalation valve, or because of the loss of FFR surface area for gas exchange if the valve is not activated. The potential for substantial CO_2 retention with N95 FFR or N95 FFR-with-valve was highlighted by 2 non-obese subjects, an otherwise healthy 42-year-old female ex-smoker (peak 60-min P_{tcCO_2} 50 mm Hg), and a 21-year-old man with no noteworthy medical history (peak 60-min P_{tcCO_2} 52 mm Hg), although both were asymptomatic. Pulmonary function testing was not carried out in the subjects, but the normal control values obtained when not wearing an FFR suggest that the FFR's effect on CO_2 retention is of some concern. It is possible that the ex-smoker subject may have had some degree of pulmonary impairment related to past tobacco use; however, the other subject had no known risk factors.

The FFR V_D is a repository for exhaled gas, which subsequently mixes with the air that enters through the FFR and is re-breathed during successive inhalations.[22] Technically, this can increase the CO_2 and decrease the O_2 entering the lungs.[23] Quantification of inspired CO_2 level is a criterion for evaluating FFR performance by governmental agencies in

Table 8. Comfort Scores

	Comfort Score* (mean ± SD)	*P*
Control at 1.7 miles/h vs control at 2.5 miles/h	1.10 ± 0.32 vs 1.30 ± 0.67	.34
Control vs FFR without valve, at 1.7 miles/h	1.10 ± 0.32 vs 1.15 ± 0.36	.77
Control vs FFR with valve, at 1.7 miles/h	1.10 ± 0.32 vs 1.44 ± 0.67	.13
Control vs FFR without valve, at 2.5 miles/h	1.30 ± 0.67 vs 1.67 ± 0.53	.07
Control vs FFR with valve, at 2.5 miles/h	1.30 ± 0.67 vs 1.43 ± 0.45	.47
FFR with valve vs FFR without valve, at 1.7 miles/h	1.44 ± 0.67 vs 1.15 ± 0.36	.20
FFR with valve vs FFR without valve, at 2.5 miles/h	1.43 ± 0.45 vs 1.67 ± 0.53	.02

* Comfort score on 1–5 scale, from most comfortable to least comfortable.
FFR = filtering facepiece respirator

Table 9. Exertion Scores

	Exertion Score* (mean ± SD)	*P*
Control at 1.7 miles/h vs control at 2.5 miles/h	0.50 ± 0.85 vs 1.05 ± 1.16	.01
Control vs FFR without valve, at 1.7 miles/h	0.50 ± 0.85 vs 0.83 ± 1.30	.13
Control vs FFR with valve, at 1.7 miles/h	0.50 ± 0.85 vs 0.88 ± 1.26	.07
Control vs FFR without valve, at 2.5 miles/h	1.05 ± 1.16 vs 1.11 ± 1.30	.78
Control vs FFR with valve, at 2.5 miles/h	1.05 ± 1.16 vs 0.93 ± 0.91	.63
FFR with valve vs FFR without valve, at 1.7 miles/h	0.88 ± 1.26 vs 0.83 ± 1.30	.65
FFR with valve vs FFR without valve, at 2.5 miles/h	0.93 ± 0.91 vs 1.11 ± 1.30	.38

* Exertion score on 1–5 scale, from no exertion to maximum exertion.
FFR = filtering facepiece respirator

Table 10. Study Subjects' Complaints About Wearing Filtering Facepiece Respirator*

	At Treadmill Speed 1.7 miles/h		At Treadmill Speed 2.5 miles/h	
	FFR With Valve	FFR Without Valve	FFR With Valve	FFR Without Valve
Breathing difficulty	1	1	0	1
Dizziness	2	0	0	1
Lightheadedness	0	0	0	1
Facial warmth	4	3	6	6
Facial sweating	0	0	0	1
Facial itching	2	1	0	1
Facial irritation	1	0	1	1
Facial pinching	0	1	2	0

* Subjects could register multiple complaints.
FFR = filtering facepiece respirator

some countries (eg, Japan), but not for NIOSH-certified FFRs. We measured time-averaged FFR V_D CO_2 and O_2 concentrations. Although that method is not as robust as volume-weighted averages for determining inhaled gas concentrations, time averages offer a view of the FFR microenvironment that is useful for comparisons with ambient gas concentrations. The timed mean mixed inhalation/exhalation FFR V_D CO_2 and O_2 values, respectively, over 1 hour, for the FFR (2.9%, 16.6%) and the FFR-with-valve (2.9%, 16.7%) did not differ significantly by work rate or FFR model, and are comparable to other studies.[18,24] Although the FFR V_D O_2 level was lower than the Occupational Safety and Health Administration's workplace standard ($<$ 19.5% O_2 is considered deficient) and the FFR V_D CO_2 level was higher ($<$ 0.5% CO_2 as an 8-h time-weighted average, is normal), these standards apply to the ambient workplace atmosphere, not to the FFR V_D. Nonetheless, breathing-environment CO_2 $>$ 3% has been associated with detrimental physiological effects,[25] and prolonged breathing of CO_2 at greater than the atmospheric level can cause symptoms (eg, headache, anxiety, and confusion) and the additional physiological stress of compensatory mechanisms. Interestingly, we found no significant FFR V_D CO_2 differences between the FFR and the FFR-with-valve, despite that the exhalation valve ostensibly prevents CO_2 buildup by allowing beneficial flow-streams that decrease FFR V_D.[17] However, the exhalation valve is activated only at a certain breathing-pressure threshold that may not have been attained under our study conditions. Irrespective of level of function, the exhalation valve may not dramatically impact FFR V_D CO_2 because, despite allowing a smaller proportion of the exhaled breath to be retained in the FFR V_D, the retained fraction is the terminal portion of

the exhalation, which has the highest CO_2 concentration (nearly equal to that of arterial blood).[25]

Moisture retention in the FFR occurs with prolonged use and may increase the breathing resistance.[26] In the current study the average moisture gain over 1 hour was 0.11 g with the FFR and 0.13 g with the FFR-with-valve ($P = .46$). This small amount of retained moisture is related to low exertion, the hydrophobicity of the studied FFRs, and the short duration of use. With an FFR model we used in the current study, other researchers found a water-vapor permeability (ie, rate of water vapor diffusion through the respirator) of 0.06 g/24 h/cm^2.[27] Although the exhalation valve is partly designed to decrease moisture buildup in the FFR, this effect may become manifest only at higher work rates than we used in the current study.

Despite significant differences in the exertion scores between controls at the 2 work rates ($P = .01$), there were no significant differences between FFR and FFR-with-valve compared to control, or for FFR compared to FFR-with-valve (see Table 9). A recent study reported that an N95 FFR-with-valve was associated with greater wear tolerability by healthcare workers than was an N95 FFR without valve during extended wear (7.7 h vs 5.8 h).[28] It may be that any benefit from an exhalation valve in the healthcare setting might come only at higher work rates (eg, as might be expected in a surge situation) or during lengthy use (eg, continuous wear for several hours).

Comfort is an important factor in healthcare worker adherence to FFR use.[28] Although the comfort scores were not significantly different when comparing control and FFR at either work rate in the current study, FFR-with-valve was rated more comfortable than FFR-without-valve at 2.5 miles/h ($P = .02$) (see Table 8). In the current study we found several comfort-related issues, including warmth, sweating, itching, and irritation (see Table 10), and similar complaints were reported with both types of FFR, despite the fact that the exhalation valve should presumably enhance comfort by eliminating heat and humidity from the FFR microenvironment. However, a recent healthcare worker study also reported no differences in absolute numbers between the users of FFR with and without exhalation valve who complained of heat,[28] which suggests that heat dissipation through the exhalation valve may only be realized at work rates above those normally experienced by healthcare workers. The number of complaints from subjects, in the present study and another study,[28] is an important issue because comfort significantly impacts the use of respiratory protective equipment.

The present study was conducted to develop baseline data on the physiological impact of FFR and FFR-with-valve on healthcare workers. Our data indicate that FFR and FFR-with-valve for 1 hour at 2 low-intensity work rates resulted in minimal additional physiological burden. This finding is supported by a recent study that found FFR tolerance among subjects with respiratory diseases.[29] Further, the lack of significant effect on S_{pO_2} and P_{tcCO_2} suggests that specific subpopulations of healthcare workers (eg, pregnant, well-controlled asthma) who are considered to be potentially adversely affected by respiratory protective equipment,[18] might safely wear FFR or FFR-with-valve for up to 1 hour at low energy expenditure, though the possibility of CO_2 retention requires further study. Our data also suggest that, at low work rates up to 1 hour, FFR-with-valve may offer no physiological advantages over FFR-without-valve, so the higher cost of FFR-with-valve may not be warranted in a low-work-rate scenario. Further human studies are required to determine the physiological burden of FFR over longer periods (eg, surge situations during respiratory infectious outbreaks) and the impact of different styles of FFR (eg, duck bill, flat fold, or cup-shaped).

Limitations

Our sample included only 10 subjects, who were young (mean age 25 y). The average age of a registered nurse in the year 2000 was 45 years; only 9.1% were $<$ 30 years of age.[30]

We examined only a few FFR models, and the study was conducted in a laboratory setting, rather than in a health-care facility. However, laboratory studies may actually represent the upper-boundary response rather than the typical responses in field studies.[29] Our use of respiratory inductive plethysmography for V_T is not as accurate as other laboratory methods (eg, pneumotachograph, spirometer), but such equipment is not readily amenable for use with FFR. Recent investigations that compared respiratory inductive plethysmography to pneumotachography[31-33] found good to excellent correlation (r^2 0.60–0.97) for V_T. Some variability (overestimation of P_{CO_2}) has been noted in P_{tcCO_2} measurements, compared to arterial CO_2 measurements, which might have been due to differences in the patient populations tested, sensor temperature, and inter-subject differences.[34] However, the Tosca 500 monitor allows for noninvasive constant monitoring of P_{tcCO_2}, and studies have demonstrated good correlation between P_{tcCO_2} and arterial CO_2 during exercise testing.[35-38]

Conclusions

Healthcare worker use of FFR and FFR-with-valve for 1 hour at clinically realistic low work rates had only mild physiological impact. At a low work rate, for up to 1 hour, FFR-with-valve may offer no physiological advantage over FFR-without-valve. The mixed inhalation/exhalation O_2 and CO_2 levels in the FFR V_D microenvironment did not meet the Occupational Safety and Health Administration's standards for workplace ambient O_2 and CO_2 concentrations. FFR comfort issues need to be addressed further to maximize healthcare worker adherence to FFR use.[28] Future studies will also need to address the possibility of CO_2 retention in susceptible

individuals and the physiological impact of FFR (with and without exhalation valve) worn for longer periods.

REFERENCES

1. Lange JH. Respiratory protection and emerging infectious diseases: lessons from severe acute respiratory syndrome. Chin Med J 2005; 118(1):62-68.
2. Martyny J, Glazer CD, Newman LS. Respiratory protection. N Engl J Med 2002;347(11):824-830.
3. Eberhard P. The design, use, and results of transcutaneous carbon dioxide analysis: current and future directions. Anaesth Analg 2007; 105(6):S48-S52.
4. Need JT, Mothershead JL. Strategic national stockpile program: implications for military medicine. Mil Med 2006;171(8):698-702.
5. Department of Labor, Occupational Safety and Health Administration. Respiratory protection: 29 CFR 1910.134. Washington: Department of Labor, Occupational Safety and Health Administration; 1998.
6. Centers for Disease Control and Prevention (CDC). Laboratory performance evaluation of N95 filtering facepiece respirators, 1996. MMWR Morb Mortal Wkly Rep 1998;47(48):1045-1049.
7. Ainsworth BE, Haskell WL, Whitt MC, Irwin ML, Swartz AM, Strath SJ, et al. Compendium of physical activities: an update of activity codes and MET intensities. Med Sci Sports Exerc 2000; 32(9):S498-S516.
8. Li Y, Tokura H, Guo YP, Wong AS, Wong T, Chung J, Newton E. Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. Int Arch Occup Environ Health 2005;78:501-509.
9. Guo YP, Yi L, Tokura H, Wong TK, Chung JWY, Gohel MD, et al. Evaluation on masks with exhaust valves and with exhaust holes from physiological and subjective responses. J Physiol Anthropol 2008;27(2):93-102.
10. Matthews JI. Exercise responses during incremental and high intensity and low intensity steady state exercise in patients with obstructive lung disease and normal control subjects. Chest 1989(1):96:11-17.
11. Szekely J, Askanazi J, Rosenbaum SH, Foster R, Milic-Emili J, Kinney JM. Ventilatory patterns during steady state and progressive exercise. Clin Physiol 1982;2:391-400.
12. Bryce E, Forrester L, Scharf S, Eshghpour M. What do healthcare workers think? A survey of facial protection equipment user preferences. J Hosp Infect 2008;68(3):241-247.
13. Borg G. Borg's perceived exertion and pain scales. Champaign, IL: Human Kinetics; 1998:49.
14. Anderson CA, Anderson KB, Deuser WE. Examining an affective aggression framework: weapon and temperature effects on aggressive thoughts, affect, and attitudes. Person Social Psychol Bull 1996; 22(4):366-376.
15. Szeinuk J, Beckett WS, Clark N, Hailoo WL. Medical evaluation for respirator use. Am J Ind Med 2000;37(1):142-157.
16. Jones JG. The physiological cost of wearing a disposable respirator. Am Ind Hyg Assoc J 1991;52(6):219-225.
17. Kao TW, Huang KC, Huang YL, Tsai TJ, Hsieh BS, Wu MS. The physiological impact of wearing an N95 mask during hemodialysis as a precaution against SARS in patients with end-stage renal disease. J Formos Med Assoc 2004;103(8):624-628.
18. Saatci E, Miller DM, Stell IM, Lee KC, Moxham J. Dynamic dead space in face masks used with noninvasive ventilators: a lung model study. Eur Respir J 2004;23(1):129-135.
19. Laferty EA, McKay RT. Physiologic effects and measurement of carbon dioxide and oxygen levels during qualitative respirator fit testing. J Chem Health Safe 2006;13:22-28.
20. Kaye J, Buchanan F, Kendrick A, Johnson P, Lowry C, Bailey J, et al. Acute carbon dioxide exposure in healthy adults: evaluation of a novel means of investigating a stress response. J Neuroendocrinol 2004;16(3):256-264.
21. Beder A, Büyükkoçak U, Sabuncuoğlu H, Keskil ZA, Keskil S. Preliminary report on surgical mask induced deoxygenation during major surgery. Neurocirugia (Astur) 2008;19(2):121-126.
22. Caretti D, Coyne KM. Unmanned assessment of respirator carbon dioxide levels: comparison of methods of measurement. J Occup Environ Hyg 2008;5(5):305-312.
23. Prevention Division, Workers Compensation Board of British Columbia. SARS: respiratory protection. Richmond, BC, Canada; June 23, 2003.
24. Huang JT, Juang VT. Evaluation of the efficiency of medical masks and the creation of new medical masks. J Intern Med Research 2007;35(2):213-223.
25. Harber P, Beck J, Brown C, Luo J. Physiologic and subjective effects of respirator mask type. Am Ind Hyg Assoc J 1991;52(9):357-362.
26. Khaw KS, Kee WDN, Tam YH, Wong MK, Lee SWY. Survey and evaluation of modified oxygen delivery devices used for suspected severe acute respiratory syndrome and other high-risk patients in Hong Kong. Hong Kong Med J 2008;14(5 Suppl):27-31.
27. Li Y, Wong T, Chung J, Guo YP, Hu JY, Guan YT, et al. In vivo protective performance of N95 respirator and surgical facemask. Am J Ind Med 2006;49(12):1056-1065.
28. Radonovich LJ Jr., Cheng J, Shenal BV, Hodgson M, Bender BS. Respirator tolerance in health care workers. JAMA 2009;301(1):36-38.
29. Harber P, Bansal S, Santiago S, Liu D, Yun D, Ng D, et al. Multidomain subjective response to respirator use during simulated work. J Occup Environ Med 2009;51(1):38-45.
30. Spratley E, Johnson A, Sochalski J, Fritz M, Spencer W. The registered nurse population: findings from the national sample survey of registered nurses: March 2000. US Department of Health and Human Services, Health Resources and Service Administration, Bureau of Health Professions, Division of Nursing. ftp://ftp.hrsa.gov/bhpr/rnsurvey2000/rnsurvey00.pdf. *Accessed February 22, 2010*
31. Clarenbach CF, Senn O, Brack T, Kohler M, Bloch KE. Monitoring of ventilation during exercise by a portable respiratory inductive plethysmograph. Chest 2005;128(3):1282-1290.
32. Witt JD, Fisher JR, Guenette JA, Cheong KA, Wilson BJ, Sheel AW. Measurement of exercise ventilation by a portable respiratory inductive plethysmograph. Respir Physiol Neurobiol 2006;154(3):389-395.
33. Fiamma MN, Samara Z, Baconnier P, Similowski T, Straus C. Respiratory inductive plethysmography to assess respiratory variability and complexity in humans. Respir Physiol Neurobiol 2007;156(2):234-239.
34. Rosner V, Hannhart B, Chabot F, Polu JM. Validity of transcutaneous oxygen/carbon dioxide pressure measurement in the monitoring of mechanical ventilation in stable chronic respiratory failure. Eur Respir J 1999;13(5):1044-1047.
35. Carter R, Banham SW. Use of transcutaneous oxygen and carbon dioxide tensions for assessing indices of gas exchange during exercise testing. Respir Med 2000;94(4):350-355.
36. Sridhar MK, Carter R, Moran F, Banham SW. Use of a combined oxygen and carbon dioxide transcutaneous electrode in the estimation of gas exchange during exercise. Thorax 1993;48(6):643-647.
37. Stege G, van den Elshout FJ, Heijdra YF, van de Ven MJ, Dekhuijzen PN, Vos PJ. Accuracy of transcutaneous carbon dioxide tension measurements during cardiopulmonary exercise testing. Respiration 2009;78(2):147-153.
38. Planes C, Leroy M, Foray E, Raffestin B. Arterial blood gases during exercise: validity of transcutaneous measurements. Arch Phys Med Rehabil 2001;82(12):1686-1691.