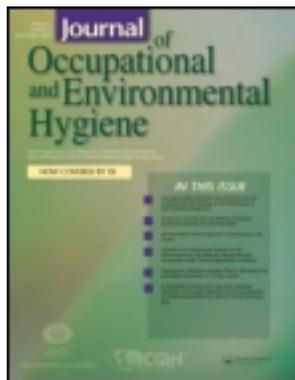


This article was downloaded by: [CDC Public Health Library & Information Center]

On: 21 September 2012, At: 06:56

Publisher: Taylor & Francis

Informa Ltd Registered in England and Wales Registered Number: 1072954 Registered office: Mortimer House, 37-41 Mortimer Street, London W1T 3JH, UK



Journal of Occupational and Environmental Hygiene

Publication details, including instructions for authors and subscription information:

<http://oeh.tandfonline.com/loi/uoeh20>

Are Exhalation Valves on N95 Filtering Facepiece Respirators Beneficial at Low-Moderate Work Rates: An Overview

Raymond J. Roberge^a

^a National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

Accepted author version posted online: 30 Jul 2012.

To cite this article: Raymond J. Roberge (2012): Are Exhalation Valves on N95 Filtering Facepiece Respirators Beneficial at Low-Moderate Work Rates: An Overview, *Journal of Occupational and Environmental Hygiene*, 9:11, 617-623

To link to this article: <http://dx.doi.org/10.1080/15459624.2012.715066>

PLEASE SCROLL DOWN FOR ARTICLE

Full terms and conditions of use: <http://oeh.tandfonline.com/page/terms-and-conditions>

This article may be used for research, teaching, and private study purposes. Any substantial or systematic reproduction, redistribution, reselling, loan, sub-licensing, systematic supply, or distribution in any form to anyone is expressly forbidden.

The publisher does not give any warranty express or implied or make any representation that the contents will be complete or accurate or up to date. The accuracy of any instructions, formulae, and drug doses should be independently verified with primary sources. The publisher shall not be liable for any loss, actions, claims, proceedings, demand, or costs or damages whatsoever or howsoever caused arising directly or indirectly in connection with or arising out of the use of this material.

Are Exhalation Valves on N95 Filtering Facepiece Respirators Beneficial at Low-Moderate Work Rates: An Overview

Raymond J. Roberge

National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, Pittsburgh, Pennsylvania

Exhalation valves (EVs) are touted as useful in dissipating humidity, heat, and carbon dioxide from the dead space of N95 filtering facepiece respirators and decreasing exhalation resistance, thereby making the respirator more comfortable and less physiologically demanding. Despite decades of use, there is limited research on the psychophysiological impact of EVs on the wearer at the current, low-moderate work rates of many workers. The available literature indicates that past and current EVs on the market decrease exhalation resistance to a variable degree and may improve dead space heat dissipation and, consequently, the temperature of the skin covered by the respirator. EVs have little substantial effect on dead space humidity, respiratory rate, heart rate, core temperature, speech intelligibility, or dead space oxygen and carbon dioxide levels at the aforementioned work rates. The studies also indicate that EVs may impact comfort and tolerance when N95 filtering facepiece respirators are worn for extended periods or at high work rates. Because comfort and tolerance impact respirator use compliance and, by extension, protection, more research into the psychophysiological impact of EVs on wearers and the development of new EVs tailored for low-moderate work rates are warranted.

Keywords N95 filtering facepiece respirators, exhalation valves, psychophysiological impact

Correspondence to: Raymond J. Roberge, National Institute for Occupational Safety and Health, National Personal Protective Technology Laboratory, 626 Cochrans Mill Road, Pittsburgh, PA 15236; e-mail: dtn0@cdc.gov.

The findings and conclusions in this manuscript are those of the author and do not necessarily represent the view of the National Institute for Occupational Safety and Health.

INTRODUCTION

The N95 class of filtering facepiece respirators (N95 FFRs) is the most commonly used respiratory protective device in the U.S. private industrial sector and health care. N95 FFR use is associated with psychophysiological stressors, such as

sensations of discomfort (e.g., warmth, increased exertion, and so on); an increase in breathing resistance; elevation of the heart rate and respiratory rate; increased facial sweat; and variable carbon dioxide retention.^(1–3) The first dust-mist mask, the forerunner to FFRs, was commercially launched in the late 1970s and featured an exhalation valve (EV) to assist with humidity elimination.⁽⁴⁾ The EV bypasses the filter media and presumably diminishes the negative impact of N95 FFR use via such mechanisms as decreased exhalation resistance and improved dissipation of exhaled moisture, heat, and carbon dioxide.⁽⁵⁾

It has been demonstrated that reduced exhalation resistance (as would occur with an EV) correlates with enhanced oxygen consumption and minute volumes at high work rates,⁽⁶⁾ but many workers in modern industrialized nations work at low-to-moderate work rates,^(7,8) wherein the impact of an EV is less defined. This may have important ramifications for purchasers of respiratory protective equipment because of the greater cost of N95 FFRs equipped with an EV (N95 FFRs/EV). Despite some early EV research,⁽⁹⁾ a review of the literature indicates that there is relatively little available research data with respect to the impact of EVs on users of respiratory protective equipment. This article will review the available data on EVs to convey information that is pertinent to stakeholders (e.g., respiratory protection program managers, users), thereby allowing them to take a more informed approach to the selection of N95 FFRs.

MATERIALS AND METHODS

A computerized literature search using Medical Subject Headings (MeSH) terms *exhalation valves*, *filtering facepiece respirators*, *N95 respirators*, *respiratory protective devices*, and *respirator physiological and psychological impact* was undertaken for the period 1950–2012 with Medline, OvidSP, Dialog, EMBase, PsycINFO, Compendex, and Google search engines. Selected articles and their bibliographies and electronic references were perused for pertinent articles.

References cited for inclusion in the review were those that included information relating to the use of EVs on respiratory protective devices, including N95 filtering facepiece respirators and those that evaluated the psychophysiological impact of wearing respiratory protective devices on the wearer.

RESULTS

A total of 430 articles and electronic references were retrieved, of which 53 were relevant and utilized for this report. Included are 42 peer-reviewed published papers, 2 abstracts, 2 government agency reports, 2 private agency reports, 1 doctoral thesis, 2 trade journal articles, 1 newsletter, and 1 manufacturer's (non-published) study. Only nine studies directly compared N95 FFRs with N95 FFRs/EV, and of these, three were non-human studies. There is a dearth of scientific data on the psychophysiological impact of EVs on wearers of N95 FFRs equipped with these devices, despite their use by millions of workers.

DISCUSSION

EV Function

For the purpose of this report, an EV is a device that allows for uni-directional exit of exhaled air through a respiratory protective device while preventing outside air from entering through the EV.⁽¹⁰⁾ Negative pressure generated in the dead space of the FFR during inspiration seats the EV to prevent air entry, and positive pressure during exhalation unseats the EV to allow a portion of the exhaled air to bypass the filter media.⁽¹¹⁾ Presumed beneficial effects of an EV are decreases in exhalation resistance, heat, humidity, and carbon dioxide from the N95 FFR dead space.^(5,12) In addition, the positive pressure buildup during exhalation, which may disrupt the facial seal of the N95 FFR, is limited by a functional EV. Some evidence suggests that EV performance may change over time due to the cyclic breathing of the wearer.⁽¹³⁾

EV Features

Structure

The EV is a simple one-way flap-type valve that consists of a valve seat, valve, and valve cover.^(11,13) EVs are thin (generally ~0.50 mm), usually composed of natural or silicone rubber or neoprene, and commonly have a round ("mushroom," "button") or flat, rectangular, or parabolic sheet configuration ("flapper").^(5,14) The valve seat (exhalation port) is situated within the body of the FFR filter material with its aperture covered by the EV. The EV is generally held in place by a centrally located post that is affixed to a cross bracket in the valve seat (round EV) or edge-pinned on one edge of the valve seat (flat rectangular and parabolic EVs). The valve cover lies outboard of the EV, comes in various configurations that generally reflect the shape of the underlying EV, is fenestrated to allow for air passage during exhalation, and serves a protective function for the delicate EV.⁽¹⁴⁾ Valve cover fenestrations are generally located on the distal half of flat (rectangular) EVs to deflect air

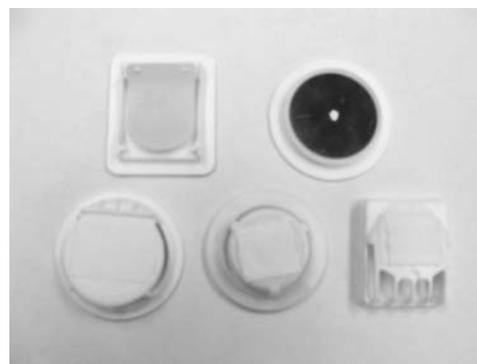


FIGURE 1. Components of N95 filtering facepiece respirator exhalation valves (clockwise from top left): edge-pinned flat (parabolic) valve on valve seat, central post-mounted round valve on valve seat, round valve cover with semicircular fenestrations (no openings superiorly), round valve cover with completely encircling fenestrations, and flat valve cover with distal and lateral fenestrations

downward and partially (distal fenestrations) or fully encircle round EVs (Figure 1). A dead space exists between the valve cover and the EV that contains some of the exhaled air that in the case of EV leakage ensures that back leakage is relatively clean.⁽¹⁵⁾ Aerosol penetration through EVs is reduced when the valve cover is in place compared with no valve cover.⁽¹⁶⁻¹⁸⁾

EV Location

N95 FFRs/EV are available with the EV positioned in central, lateral, distal, or superior aspects of the respirator, each location offering advantages and disadvantages that the user may wish to consider. At sedentary levels⁽¹⁹⁾ or low work rates, most individuals are nasal breathers, with the switch from nasal to oronasal breathing occurring at activity levels associated with breathing volumes ~35 L/min.⁽²⁰⁾ Respiratory protective device workloads increase the proportion of oral vs. nasal breathing⁽²¹⁾ so that a centrally positioned EV (the most common placement) is aligned with the oral cavity such that the streamlined airflows necessary for activation of the EV are exhaled in the most direct trajectory.⁽³⁾ For the wearers who maintain nasal breathing, the exhaled air is directed in a downward airflow profile^(22,23) rather than directly at a centrally placed EV. Nasal breathers' airflow could theoretically benefit from N95 FFR with distally placed EV, but facial sweat is more likely to accumulate in dependent areas and can impair valve seating.⁽¹⁵⁾

Laterally placed EVs are not directly aligned with the central path of exhaled air; however, because the lateral pathway from the EV to the mouth is longer than that with a centrally located EV, theoretically, there may be less chance of inhalation of contaminants if EV leakage occurs.⁽¹⁸⁾ Some flat fold N95 FFRs come with a round EV with encircling fenestrations positioned superiorly on the upper fold that can result in directing some of the exhaled air upward toward the

eyes and could potentially result in fogging corrective lenses or protective eyewear (e.g., goggles, eye shields, and so on).

Impact of EV on N95 FFR Dead Space Parameters Humidity

Saturation with water vapor from the airways results in exhaled air with a relative humidity (RH) approaching 100%. The amount of moisture expelled with each exhalation varies with rate and depth of respiration but, at sedentary activity, averages 100 $\mu\text{L}/\text{min}$ (range 40–300 $\mu\text{L}/\text{min}$).⁽²⁴⁾ At a tidal volume of 500 mL and normal exhaled air moisture content of 4–5%, each exhalation results in the expulsion of 20–25 μL of water vapor that, at a normal exhaled air temperature of 34.0°C,⁽²⁵⁾ is equivalent to $\sim 7.5\text{--}9.4 \times 10^{-4}$ grams of water expelled per exhalation. Some of this moisture is retained in the dead space, within the filter material, and on the inner surface of the EV. Inspired air will admix with the N95 FFR dead space air and, depending on its ambient humidity, modify the dead space RH level to variable degree.

The first dust-mist mask (as previously mentioned, the forerunner of the FFR) that was developed commercially included an EV that was employed specifically for the easy elimination of exhaled humidity.⁽⁴⁾ This function is not an unreasonable assumption because the moist air that escapes via the EV is not trapped in the meshwork pores of the filter fibers. However, there have been mixed results from studies assessing the value of an EV in moisture dissipation. Hayashi and Tokura,⁽²⁶⁾ evaluating two cup-shaped N95 FFR models from the same manufacturer, that differed only in the presence or absence of an EV (flap type), reported significantly lower N95 FFR/EV dead space humidity levels (data not reported, but graph data indicate decreases of $\sim 1\text{--}4 \text{ gm}/\text{m}^3$ [i.e., 0.000001–0.000004 gm/cm^3]) for subjects wearing protective clothing (GoreTex) while performing three series of 15-min stepping exercises (21 steps per min) interspersed with 5-min rest periods at ambient conditions of 28°C and 60% RH. Assuming an average N95 FFR functional dead space volume of 123 mL when worn,⁽²⁷⁾ Hayashi and Tokura's graph data would indicate a decrease of $\sim 1.2\text{--}4.9 \times 10^{-4}$ gm in dead space humidity for an N95 FFR/EV compared with an N95 FFR over the course of 1 hr at low-to-moderate work rates, values that were statistically significant but perhaps of limited physiological impact.⁽²⁶⁾

Conversely, one recent study of 17 subjects treadmill exercising (5.6 km/h) at mean ambient conditions of 21.4°C and 23.5% RH, wearing two manufacturers' models each of N95 FFRs and N95 FFRs/EV (whose only feature difference was the presence of the EV and its shape [flat vs. round EV]), showed no significant difference in dead space RH levels at 1 hr or 2 hr, as measured by a wireless sensor attached to the inner surface of the FFRs.⁽²⁸⁾ Cooling of the relatively non-porous EV by the inhalation air currents, as well as the temperature gradient between the N95 FFR deadspace temperature and ambient temperatures,⁽²⁹⁾ can result in condensation to form on its inner surface that increases deadspace moisture and variably offsets moisture loss through the EV.^(28,30) Sweat accumulation under the N95 FFR can also negate any presumed

beneficial effects of an EV on decreasing deadspace humidity levels.⁽²⁸⁾ Last, the minimum of $\sim 30 \text{ L}/\text{min}$ airflow, needed to develop the streamlined airflows during exhalation that are necessary for EV activation,⁽³¹⁾ may be absent at sedentary levels or at low work rates.^(32,33) Thus, the actual impact of the EV on moisture elimination may be minimized by virtue of the enhanced properties of modern N95 FFRs (i.e., thinness, porosity, hydrophobicity) that optimize moisture expulsion at the lesser breathing volumes associated with low-to-moderate work rates compared with high work rates.

Temperature

The N95 FFR dead space temperature is derived from the combined inputs of the temperature of the exhaled air, interference with convection and evaporation processes of the facial skin covered by the N95 FFR, and the temperature of the ambient air that is entrained with inhalation.⁽³⁴⁾ Prior investigations at varying work rates have shown that wearing an FFR results in $\sim 7.0^\circ\text{C}$ increase in dead space temperature over ambient temperature,^(35,36) but relatively few studies have evaluated the thermoregulatory impact of EVs. Hayashi and Tokura⁽²⁶⁾ reported significantly lower dead space temperature for an N95 FFR/EV compared with an N95 FFR (data not reported, but graph data indicate difference of $\sim 0.1\text{--}0.4^\circ\text{C}$). Roberge et al.⁽²⁸⁾ noted significantly lower dead space temperatures, averaging $\sim 0.8^\circ\text{C}$, for two models of N95 FFRs/EV compared with two similar models of N95 FFRs over 1 hr but noted no significant difference between 1-hr or 2-hr N95 FFR/EV dead space temperatures. A manufacturer's (non-published) investigation,⁽³⁷⁾ utilizing a breathing mannequin with 85 L/min flow rate, reported lower temperatures for N95 FFRs/EV compared with N95 FFRs that were similar, save for having an EV (data not reported, but graph data indicate N95 FFR/EV were associated with $\sim 4^\circ\text{C}$ lower dead space temperatures).

Carbon Dioxide

Carbon dioxide (CO_2) is a metabolic product expelled during exhalation, but a variable level is maintained within the dead space of the N95 FFR and rebreathed with subsequent inhalations. Recent human studies at low-moderate work rates have shown no differences in levels of dead space CO_2 for N95 FFRs/EV compared with N95 FFRs.^(3,38) One study utilizing a breathing mannequin also noted no difference in N95 FFRs with or without an EV with respect to inhaled CO_2 levels.⁽³⁹⁾ This absence of significant effect for the EV may be attributable to a lack of adequate breathing volume at these low-moderate work rates to fully activate the EV, loss of some surface area for gas exchange when an EV is non-functional, and the higher CO_2 levels of the terminal component of exhaled air (nearly that of alveolar CO_2) that remains in the FFR dead space.^(3,23,40) A possible impact of EVs on N95 FFR dead space CO_2 levels may be manifest only at high work rates and breathing volumes, but this remains to be determined.

Oxygen

The ambient oxygen (O_2) that traverses the filter media of the N95 FFR during inhalation is subsequently admixed with dead space O_2 remaining from the previous exhalation. Diminished N95 FFR dead space O_2 levels have previously been documented in a non-human study, but N95 FFRs/EV were not investigated.⁽⁴¹⁾ Recent human studies have shown similarly decreased dead space O_2 levels compared with ambient air for N95 FFRs and N95 FFRs/EV over 1 hr at low-moderate work rates.^(3,38) These lowered dead space O_2 levels were not associated with any meaningful decrements in the subjects' O_2 saturation.^(3,38)

Effects on FFR Properties

Exhalation Pressure

EVs decrease expiratory resistance by allowing exhaled air to bypass N95 FFR filter media. Prior investigation of EVs (on air-purifying respirators) has shown that flap-type EVs studied have approximately twice the expiratory resistance (i.e., 12.1 mm H_2O pressure) of round EVs studied at 40 L/min flow.⁽¹⁶⁾ An earlier investigation reported that dust-mist masks with an EV, the forerunners of FFRs, were associated with <5.1 mm H_2O expiratory pressure.⁽⁹⁾ One study, that utilized an Automated Breathing and Metabolic Simulator (ABMS) as a human surrogate at a breathing volume of 40 L/min over 4 hr, reported only a 0.57 mm H_2O decrement in exhalation pressure for N95 FFRs/EV compared with N95 FFRs.⁽⁴²⁾ Limited data from another ABMS study indicated that the exhalation pressures of one model of N95 FFR/EV, at breathing volumes of 25 L/min and 40 L/min, were approximately one-third to one-half that of three models of N95 FFRs.⁽³²⁾ A manufacturer's (non-published) study, utilizing a breathing mannequin, indicated that, at a high exhalation flow (160 L/min), N95 FFRs/EV manifested lower exhalation pressures than N95 FFRs (data not reported, but graph data indicate ~0.5–0.7 millibars (5–7 mm H_2O pressure)).⁽³⁷⁾ The streamlined airflows generally required to activate EVs may be absent at low-moderate work rates. Improved EVs on N95 FFRs, which are reported as functioning at lower breathing volumes, have been developed and patented but are not yet available commercially.⁽⁴³⁾

Moisture Retention

Human studies,^(3,28,38) and one non-human study using an ABMS,⁽⁴²⁾ have noted moisture retention of <0.30 gm over 1 hr for N95 FFRs and N95 FFRs/EV, with no significant difference between models. This lack of moisture retention reflects the enhanced water vapor permeability of modern N95 FFRs, estimated at 0.06 gm/24 h/cm² for a cup-shaped model,⁽²⁹⁾ that is partially related to their thinness subsequent to the incorporation of electrical charges (electret) into the filter material to enhance particle capture performance.⁽⁴⁾ Also, although some current N95 FFR filters are (at least partially) composed of some hydrophilic materials that retain moisture⁽⁴⁴⁾ and could potentially result in higher dead space humidity, most modern N95 FFR filters are composed of polypropylene, a highly

hydrophobic material.⁽⁴²⁾ These properties of N95 FFR filters likely minimize the impact of the moisture reduction effects of EVs at low-moderate work rates.

Surface Temperatures

N95 FFR surface temperatures are generally lower than deadspace temperatures and result from the combined exposure to expired and ambient air temperature and humidity and breathing rate and volume, as well as material properties of the FFR filter (e.g., thickness, porosity, and so on). Monaghan et al.⁽⁴⁵⁾ used thermal imaging to evaluate two models of N95 FFRs/EV with two counterpart models of N95 FFRs (similar in all respects except for the presence of the EV) at sedentary breathing volumes and noted, paradoxically, lower surface temperatures for the N95 FFRs that approached statistical significance ($p = 0.05$). Lower surface temperatures were reported for a prototype laminated polypropylene FFR (not N95 FFRs) with dual inhalation and exhalation valves compared with a similar model that had combined exhalation/inhalation holes (data not reported, but graph data indicate ~1–1.2°C difference in temperatures).⁽²⁾ A manufacturer's (non-published) study comparing N95 FFRs and N95 FFRs/EV utilized thermal imaging to present visual images that N95 FFR surfaces are cooler with an EV, but no data were reported.⁽³⁷⁾ It is plausible that EVs may only have an ameliorating effect on N95 FFR surface temperatures at higher work rates, but this requires scientific verification.

Psychophysiological Impact

Facial Skin Temperature

Under normal conditions, skin temperature is modulated by the temperature and humidity of the surrounding air to which it is exposed.⁽⁴⁶⁾ The heat perception sensed by the wearer on the facial skin covered by an FFR, the "respirator heat index," is a composite effect of the interaction of dead space heat and humidity that has been shown to reach 54°C when wearing an N95 FFR over the course of 1 hr at a low-moderate work rate.⁽²⁸⁾ The barrier effect of N95 FFRs interferes with heat convection and evaporation of the facial skin covered by the respirator that further serves to elevate skin temperatures.⁽³⁴⁾ In one exercise study, skin temperatures under an N95 FFR/EV were significantly lower than with an N95 FFR (data not reported, but graph data indicate a difference at 1 hr of ~0.33°C).⁽²⁶⁾ Another study reported mean skin temperatures under the respirator of 34.18°C and 33.53°C, respectively, for N95 FFRs and N95 FFRs/EV over 1 hr at a low-moderate work rate.⁽²⁸⁾ The lower dead space temperatures associated with N95 FFRs/EV compared with N95 FFRs translate to lower temperatures for facial skin covered by FFRs.^(26,28)

Core Temperature

Respiratory heat loss accounts for ~10% of total heat loss from the body.⁽⁴⁷⁾ Hayashi and Tokura⁽²⁶⁾ noted no significant differences in rectal temperatures or tympanic temperatures with N95 FFRs/EV compared with N95 FFRs during low-moderate exercise studies at 28°C and 60% RH. Similarly,

N95 FFRs and N95 FFRs/EV did not differ significantly in the mild increase noted in core temperature ($\leq 0.12^{\circ}\text{C}$) over 1 hr at a low-moderate work rate measured by an ingestible core temperature pill.⁽⁴⁸⁾ Respiratory heat loss is a relatively minor component of total body heat loss ($\sim 10\%$) and, as such, the impact of N95 FFRs, with or without an EV, would not be expected to be significant. Further, at low-moderate work rates for periods of up to 1 hr, the observed increase in core temperature may be more related to the work rather than N95 FFR use.⁽⁴⁸⁾

Cardiopulmonary Parameters

Recent studies at low-moderate work rates over 1 hr have shown no differences between N95 FFRs and N95 FFRs/EV with respect to oxygen saturation, transcutaneous CO_2 levels (tcPCO₂), heart rate, tidal volume, ventilation, and respiratory rate.^(3,26,38,49) One low-moderate work rate study examining differences between two models of N95 FFRs/EV and two models of similar N95 FFRs (that differed only in the absence of the EV) noted a lower level of tcPCO₂ associated with one model of N95 FFR/EV, compared with its counterpart N95 FFR, that was statistically significant but quantitatively of limited clinical impact (i.e., tcPCO₂ increases ranging from 0.4–3.9 mm Hg over 1 hr).⁽⁴⁹⁾ The increase in cardiopulmonary parameters (e.g., heart rate, respiratory rate) when wearing N95 FFRs at low-moderate work rates is likely related to the work and not the respirator.⁽⁴⁹⁾

Subjective Measures of Comfort and Tolerance

Comfort and tolerance are critical issues in compliance with the use of protective facemasks and, by extension, worker protection. If workers feel comfortable wearing N95 FFRs, they are more likely to use them appropriately. Subjective measures of increased humidity, hotness, and breathing resistance, but not for overall discomfort, were reported for a prototype FFR with dual exhalation valves compared with a prototype FFR with combined inhalation/exhalation holes, but these were not N95 FFRs.⁽²⁾ Subjective measures of exertion and heat during 1 hr of exercise at a low-moderate work rate while wearing N95 FFRs and N95 FFRs/EV were qualitatively similar with exertion perception scores indicating “fairly light exertion” and heat perception scores ranging from “neutral” to “slightly hot.”⁽⁴⁸⁾

Another study reported no significant differences in exertion scores between N95 FFRs and N95 FFRs/EV during treadmill exercise at low work rates over 1 hr, but comfort was significantly greater with the N95 FFRs/EV at a 2.5 mph (4.02 km/h) work rate.⁽³⁾ Roberge et al.⁽³⁸⁾ reported no difference in exertion and comfort scores at low work rates over 1 hr when comparing N95 FFRs and N95 FFRs/EV covered externally with a surgical mask. Hayashi and Tokura⁽²⁶⁾ noted no difference in subjective sensations between N95 FFRs and N95 FFRs/EV. Significantly improved tolerance to N95 FFRs/EV compared with N95 FFRs ((7.7 hr vs. 5.8 hr) worn by health care workers has been reported,^(50,51) suggesting that

EV-related issues of N95 FFR tolerance and comfort may be impacted by length of wear.

Communication

All respiratory protective devices impact communication to some degree by attenuation and distortion of sound and by restricting lower jaw articulation.⁽¹⁵⁾ One study of speech intelligibility of health care workers reported no significant differences between N95 FFRs, N95 FFRs/EV, and surgical masks compared with controls, but N95 FFRs/EV had (minimally) lower modified rhyme test scores (a measure of the percentage of words heard correctly by listeners) compared with N95 FFRs.⁽⁵²⁾ Another study, evaluating speech intelligibility onboard stationary rescue aircraft with the motor running, noted no statistically significant difference for speech intelligibility between N95 FFRs and N95 FFRs/EV.⁽⁵³⁾ Therefore, the available data seem to indicate no benefit of EVs for speech intelligibility of N95 FFRs.

CONCLUSIONS

There is limited published scientific data available with respect to the effect of an EV on the psychophysiological impact of wearing an N95 FFR at low-moderate work rates. Available data (Table I) suggest that, compared with

TABLE I. Studies Comparing the Effects of FFRs With and Without Exhalation Valves on Associated Parameters at Low-Moderate Work Rates

| Studied Parameter | Significant Impact | No Significant Impact |
|---------------------------------|---------------------------------|-----------------------|
| Exhalation resistance | 5,32,37 ^A | 42 |
| Moisture retention | | 3,28,38,42 |
| Deadspace humidity | 26 | 28 |
| Deadspace carbon dioxide | | 3,38,39 |
| Dead space oxygen | | 3,38 |
| Dead space temperature | 26,28,37 ^A | |
| Core temperature | | 26,48 |
| Covered facial skin temperature | 26,48 | |
| Respirator surface temperature | 2, ^B 37 ^A | 45 |
| Respiratory rate | | 3,38,49 |
| Heart rate | | 3,26,38,49 |
| Oxygen saturation | | 3,38,49 |
| Tidal volume | | 3,38 |
| Transcutaneous carbon dioxide | 49 ^C | 3,38,49 ^C |
| Subjective indices of comfort | 50,51 | 3,26,38,48 |
| Verbal communication | 52 ^C | 52, ^C 53 |

Note: Studies indicated by reference numbers.

^ANon-published manufacturer's study.

^BPrototype filtering facepiece respirator.

^COne of two tested models of N95 filtering facepiece respirators with an exhalation valve.

N95 FFRs, N95 FFRs/EV improve heat elimination from the respirator dead space that also results in lower temperature of covered facial skin. The impact of EVs on dead space humidity is not resolved completely but in general appears not to be quantitatively substantial at low-moderate work rates for the models studied to date. FFR dead space O₂ and CO₂ levels are not impacted significantly by the presence of an EV, and exhalation resistance is decreased variably by EVs. Core temperature is not impacted significantly by wearing FFRs and, thus, is not ameliorated by wearing N95 FFRs/EV. At low-moderate work rates, an N95 FFR impacts heart rate and respiratory rate negligibly, and consequently, the impact of an EV on those parameters is likewise negligible. Speech intelligibility is not impacted by the presence of an EV. With lengthy periods of wear, N95 FFR/EV may be perceived subjectively as more comfortable than N95 FFR. The limited data available with respect to the overall impact on users of N95 FFRs indicate that additional research is warranted in areas of associated physiological burden, comfort, and tolerance and the development of better EV technology optimized for low-moderate work rates.

ACKNOWLEDGMENTS

The authors thank Dr. Ronald Shaffer, Dr. W. Jon Williams, Tim Rehak, and Tom Pouchot for their manuscript review and suggestions.

REFERENCES

1. Baig, A.S., C. Knapp, A.E. Eagan, and L.E. Radonovich, Jr.: Health care workers' views about respirator use and features that should be included in the next generation of respirators. *Am. J. Infect. Control* 38(1):18–25 (2010).
2. Guo, Y.P., L. Yi, H., Tokura, et al.: Evaluation on masks with exhaust valves and with exhaust holes from physiological and subjective responses. *J. Physiol. Anthropol.* 27(2):93–102 (2008).
3. Roberge, R.J., A. Coca, W.J. Williams, J.B. Powel, and A.J. Palmiero: Physiological impact of the N95 filtering facepiece respirator on healthcare workers. *Respir. Care* 55(5):569–577 (2010).
4. Herris, W.P.: "How Regulation and Innovation Have Shaped Respiratory Protection." Available at http://ehstoday.com/ppe/respirators/regulation_innovation_shaped/ (accessed January 26, 2012).
5. Garvey, D.: When not to use FFRs. *Occup. Health Safety* 79(3):24–26 (2010).
6. Caretti, D.M., W.H. Scott, and A.T. Johnson: Work performance when breathing through different respirator exhalation resistances. *Am. Ind. Hyg. Assoc. J.* 62(4):411–415 (2001).
7. Meyer, J.P., M. Hery, J. Herrault, et al.: Field study of subjective assessment of negative pressure half-masks. Influence of work conditions on comfort and efficiency. *Appl. Ergon.* 28(5–6):331–338 (1997).
8. Harber P., S. Bansal, S. Santago, et al.: Multidomain subjective response to respirator use during simulated work. *J. Occup. Environ. Med.* 51(1):38–45 (2009).
9. Laird, I.S.: "The Physiological Costs of Wearing Respiratory Protective Devices." Ph.D. diss., Massey University, New Zealand, 1995.
10. Committee on the Development of Reusable Facemasks for Use During an Influenza Pandemic: *Reusability of Facemasks During an Influenza Pandemic: Facing the Flu*. Washington, D.C.: The National Academies Press, 2006.
11. Brueck, S., M. Lehtimaki, U. Krishnan, and K. Willeke: Method development for measuring respirator exhalation valve leakage. *Appl. Occup. Environ. Hyg.* 7(3):174–179 (1992).
12. Laferty, E.A., and R.T. McKay: Physiologic effects and measurement of carbon dioxide and oxygen levels during qualitative respirator fit testing. *J. Chem. Health Safety.* 13(5):22–28 (2006).
13. Delaney, L.J., R.T. McKay, and A. Freeman: Determination of known exhalation valve damage using a negative pressure user seal check method on full facepiece respirators. *Ann. Occup. Environ. Hyg.* 18(4):237–243 (2003).
14. Kuo, Y.-M., C.-Y. Lai, and C.-C. Chen: Evaluation of exhalation valves. *Ann. Occup. Hyg.* 49(7):563–568 (2005).
15. Wetherell, A.: "The UK General Service Respirator." Available at <http://www.dtic.mil/cgi-bin/GetTRDoc?AD=ADA452235> (accessed January 12, 2012).
16. Burgess, W.A., and D.E. Anderson: Performance of respirator expiratory valves. *Am. Ind. Hyg. Assoc. J.* 28:216–223 (1967).
17. Bellin, P., and W. Hinds: Aerosol penetration through respirator exhalation valves. *Am. Ind. Hyg. Assoc.* 51(10):555–560 (1990).
18. Koh, F.C., A.T. Johnson, and T.E. Rehak: Inward leakage in tight-fitting PAPRs. *J. Environ. Public Health* 14(2):E19–26 (2011).
19. Maxwell, D.L., D. Cover, and J.M.B. Hughes: Effect of respiratory apparatus on timing and depth of breathing in man. *Respiration Physiol.* 61(2):255–264 (1985).
20. O'Kroy, J.A., T. James, J.M. Miller, D. Torok, and K. Campbell: Effects of an external nasal dilator on the work of breathing during exercise. *Med. Sci. Sports. Exerc.* 33(3):454–458 (2001).
21. Harber, P., J. Beck, and J. Luo: Study of respirator effect on nasal-oral flow partition. *Am. Ind. Hyg. Assoc. J.* 32(4):408–412 (1997).
22. Murthy, R., and I. Pavlidis: Noncontact measurement of breathing function. *Eng. Med. Biol. Mag.* 25(3):57–67 (2006).
23. Murakami, S.: Analysis and design of micro-climate around the human body with respiration by CFD. *Indoor Air* 14(Suppl 7):144–156 (2004).
24. Horvath, I., J. Hunt, and P.J. Barnes: Exhaled breath condensate: Methodological recommendations and unresolved questions. *Eur. Respir. J.* 26(3):523–548 (2005).
25. Winslow, C.-E. A., L.P. Herrington, and J.H. Nelbach: The influence of atmospheric temperature and humidity upon the dryness of the oral mucosa. *Am. J. Hyg.* 35:27–39 (1942).
26. Hayashi, C., and H. Tokura: The effects of two kinds of mask (with and without exhaust valve) on clothing microclimates inside the mask in participants wearing protective clothing for spraying pesticides. *Int. Arch. Occup. Environ. Health* 77(1):73–78 (2004).
27. Lee, S.-A., A. Adhikari, S.A. Grinshpun, et al.: Respiratory protection provided by N95 filtering facepiece respirators against airborne dust and microorganisms in agricultural farms. *J. Occup. Environ. Hyg.* 2:577–585 (2005).
28. Roberge, R.J., J.-H. Kim, and S.M. Benson: N95 filtering facepiece respirator deadspace temperature and humidity. *J. Occup. Environ. Hyg.* 9:166–171 (2012).
29. Li, Y., T. Wong, J. Chung, et al.: In vivo protective performance of N95 respirator and surgical facemask. *Am. J. Ind. Med.* 49(12):1056–1065 (2006).
30. Roberge, R.J., A. Coca, W.J. Williams, J.B. Powell, and A.J. Palmiero: Reusable elastomeric air-purifying respirators: Physiologic impact on health care workers. *Am. J. Infect. Control* 38(5):381–386 (2010).
31. Brosseau, L.M.: "Update on Respirators and Surgical Masks: Review of Literature (2007–2010)." Available at <http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/PPECurrentResearch/2010-JUN-3/Brosseau%20-%20Panel%202.pdf> (accessed February 8, 2012).
32. Vojtko, M.R., M.R. Roberge, R.J. Vojtko, and R.J. Roberge: Effect on breathing resistance of a surgical mask worn over a N95 filtering facepiece respirator. *J. Int. Soc. Resp. Protect.* 25:1–8 (2008).

33. **McKay, R.:** "Filtering Facepieces With Exhalation Valves: Are They Any Cooler and More Comfortable?" Available at http://www.isrp.com/americas/docs/rpn_100110.pdf (accessed February 14, 2012).
34. **Roberge, R.J., J.-H. Kim, and A. Coca.:** Protective facemask impact on human thermoregulation: An overview. *Ann. Occup. Hyg.* 56(1):102–112 (2012).
35. **Jones, J.G.:** The physiological cost of wearing a disposable respirator. *Am. Ind. Hyg. Assoc. J.* 52(6):219–225 (1991).
36. **Li Y., H. Tokura, Y.P. Guo, et al.:** Effect of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations. *Int. Arch. Occup. Environ. Health* 78(6):501–509 (2005).
37. **3M:** "Make a Cool Decision." Available at http://solutions.3m.com/3MContentRetrievalAPI/BlobServlet?locale=en_GB&lmd=1297086776000&assetId=1273676751538&assetType=MMM-Image&blobAttribute=ImageFile (accessed February 13, 2012).
38. **Roberge, R.J., A. Coca, W.J. Williams, A.J. Palmiero, and J.B. Powell:** Surgical mask placement over N95 filtering facepiece respirators: Physiological effects on healthcare workers. *Respirology* 15(3):516–521 (2010).
39. **Suzuki, K., A. Ogawa, and Y. Matsumura:** "Influencing Factors of Carbon Dioxide Concentration Increase of Filtering Respirators." Available at http://www.isrp.com.au/isrpcom/journal/jp_abstracts/suzuki.htm (accessed February 13, 2012).
40. **Harber, P., J. Beck, C. Brown, and J. Luo:** Physiologic and subjective effects of respirator mask type. *Am. Ind. Hyg. Assoc. J.* 52(9):357–362 (1991).
41. **Sinkule, E., N. Turner, and S. Hota:** "Automated Breathing and Metabolic Simulator (ABMS) CO₂ Test for Powered and Nonpowered Air-Purifying Respirators, Airline Respirators and Gas Masks." Abstract no. 227. Paper presented at *American Industrial Hygiene Conference and Expo*, Dallas, Texas, May 10–15, 2003.
42. **Roberge, R.J., E. Bayer, J.B. Powell, A. Coca, M.J. Roberge, and S.M. Benson:** Effect of exhaled moisture on breathing resistance of N95 filtering facepiece respirators. *Ann. Occup. Hyg.* 54(6):671–677 (2010).
43. **Martin, P.G., and X. Jianxian:** 2003. Filtering face mask that has a resilient seal surface in its exhalation valve. US Patent 7,188,622, filed Jun. 19, 2003, and issued Mar. 13, 2007.
44. **Fisher, E.M., J.L. Williams, and R.E. Shaffer:** Evaluation of microwave steam bags for the decontamination of filtering facepiece respirators. *PLoS ONE* 6(4):e18585 (2011).
45. **Monaghan, W.D., M.R. Roberge, M. Rengasamy, and R.J. Roberge:** Thermal imaging comparison of maximum surface temperatures achieved on N95 filtering facepiece respirators with and without exhalation valves at sedentary breathing volumes. *J. Int. Soc. Resp. Protect.* 26:12–19 (2009).
46. **Nielsen, R., A.R. Gwosdow, L.G. Berglund, and A.B. DuBois:** The effect of temperature and humidity levels in a protective mask on user acceptability during exercise. *Am. Ind. Hyg. Assoc. J.* 48:639–645 (1987).
47. **Hanson, R.D.G.:** Respiratory heat loss at increased core temperature. *J. Appl. Physiol.* 37(1):103–107 (1974).
48. **Roberge, R., S. Benson, and J.-H. Kim:** Thermal burden of N95 filtering facepiece respirators. *Ann. Occup. Hyg.* 56(7):808–814 (2012).
49. **Kim, J.-H., S.M. Benson, and R.J. Roberge:** Pulmonary and heart rate response to wearing N95 filtering facepiece respirators. *Am. J. Infect. Control.* [In Press]
50. **Radonovich, L.J. Jr., J. Cheng, B.V. Shenal, M. Hodgson, and B.S. Bender:** Respirator tolerance in health care workers (Research Letter). *J. Am. Med. Assoc.* 301(1):38–38 (2009).
51. **Shenal, B.V., L.J. Radonovich Jr., J. Cheng, M. Hodgson, and B.S. Bender:** Discomfort and exertion associated with prolonged wear of respiratory protection in a health care setting. *J. Occup. Environ. Hyg.* 9:59–64 (2012).
52. **Radonovich, L.J. Jr., R. Yanke, J. Cheng, and B. Bender:** Diminished speech intelligibility associated with certain types of respirators worn by healthcare workers. *J. Occup. Environ. Hyg.* 7:63–70 (2010).
53. **Thomas, F., C. Allen, W. Butts, C. Rhoades, C. Brandon, and D.L. Handrahan:** Does wearing a surgical facemask or N95-respirator impair radio communication? *Air Med. J.* 30(2):97–102 (2011).