Respiratory Physiology & Neurobiology 181 (2012) 29–35

Contents lists available at SciVerse ScienceDirect

Respiratory Physiology & Neurobiology

journal homepage: www.elsevier.com/locate/resphysiol

Absence of consequential changes in physiological, thermal and subjective responses from wearing a surgical mask

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ARTICLE INFO

Article history:
Accepted 24 January 2012

Keywords:
Surgical mask
Thermal burden
Physiological impact
Subjective perceptions

ABSTRACT

Twenty subjects treadmill exercised at 5.6 km/h for 1 h with and without wearing a surgical mask while being monitored for heart rate, respiratory rate, oxygen saturation, transcutaneous CO_2, SpO_2, core and skin temperatures, mask deadspace heat and relative humidity, and skin temperature under the mask. Rating scales were utilized for exertion and heat perceptions. Surgical mask use resulted in increases in heart rate (9.5 beats/min; $p < 0.001$), respiratory rate (1.6 breaths/min; $p = 0.02$), and transcutaneous carbon dioxide (2.17 mm Hg; $p = 0.0006$), and decreased temperature of uncovered facial skin (0.40 °C; $p = 0.03$). The 1.76 °C increase in temperature of the skin covered by the mask was associated with a mask deadspace apparent heat index of 52.9 °C. Perceptions of heat were neutral to slightly hot, and for exertion ranged from very, very light to fairly light. Surgical mask use for 1 h at a low-moderate work rate is not associated with clinically significant physiological impact or significant subjective perceptions of exertion or heat.

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1. Introduction

The concept and use of the surgical mask (SM) was first introduced in the nineteenth century in Germany (Mikulicz, 1897). The primary purpose of a SM was to protect the surgical patient from pathogens expelled on droplets from the nose and mouth of surgical personnel during speech, coughing and sneezing, but more recently SMs have been advocated as a protective barrier for the wearer from splashes and spills of body fluids (Lipp and Edwards, 2005). The HIV epidemic and concerns over bloodborne pathogens brought about the classification of SMs as personal protective equipment (PPE) by the U.S. Occupational Safety and Health Administration (OSHA) (Belkin, 1996). SMs are classified as protective facemasks (PFs) but are not considered respiratory protective equipment because they do not seal to the face. SMs (also referred to as medical masks, dental masks, procedure masks, laser masks, isolation masks) have become among the most commonly used PPE in the healthcare environment, and use is likely to be accentuated during outbreaks of respiratory infectious diseases (e.g., pandemic influenza, etc.) (Phin et al., 2009). In many countries, SMs are also frequently used by the public during such outbreaks, making SMs among the most used PPE worldwide. All types of PFs are associated with increased thermal perceptions (body, face) that can make them uncomfortable to wear. In a large survey of health care workers, Nickell et al. (2004) reported that 85% of respondents found that wearing a PF was particularly bothersome. Although SM worn by health care workers over an eight-hour shift were associated with less discomfort and exertion than filtering facepiece respirators (FFRs) (Shenal et al., 2012), almost one-half were unable to wear SM for the full shift, despite interposed break periods (Radonovich et al., 2009). MacIntyre et al. (2009), in a study evaluating the use of PFs to control the spread of respiratory virus in households, reported first day adherence of 38% for SMs and 46% for FFRs that declined significantly over 5 days of use and was attributed to discomfort by 50% of wearers. Discomfort is a major reason for noncompliance with PF use and, by extension, exposes an individual to increased risk of infection. Despite more than a century of use, relatively little scientific evaluation of the burden of SM wear has been accomplished. This study, part of a broad investigation by the National Personal Protective Technology Laboratory (NPPTL) of the National Institute for Occupational Safety and Health (NIOSH) evaluating the use of PFs (NIOSH, 2010), reports on the physiological, thermal and subjective impact of a SM on the wearer. Other data from the study have been published in a companion paper (Roberge et al., 2012).

2. Materials and methods

2.1. Ethical approval

The study was carried out in accordance with the Code of Ethics of the World Medical Association (*Declaration of Helsinki*) and was approved by the NIOSH Human Subjects Review Board, with all subjects providing oral and written informed consent. All subjects

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1569-9048/$ – see front matter. Published by Elsevier B.V.
doi:10.1016/j.resp.2012.01.010

were informed that they could withdraw from the study at any time without prejudice.

2.2. Participants

Twenty healthy subjects (13 men, 7 women), all of whom were non-smokers and 11 with no prior experience wearing a PF, were recruited and tested over a three month period. Subject demographics (standard deviations) were: age 23.0 (2.8) years, height 175.8 (9.5) cm, weight 77.6 (15.9) kg, and Body Mass Index 25.0 (4.1) kg/m^2. All subjects had a screening history and physical examination by a licensed physician, a negative urine test for drugs-of-abuse, and a negative urine pregnancy test (women subjects).

2.3. Surgical mask characteristics and laboratory conditions

A Kimberly-Clark Technol 49214 pleated SM (Kimberly-Clark, Irving, TX), constructed of three hydrophobic polypropylene layers, was selected for the study because the company has a leading U.S. market share for SM in healthcare (Kimberly-Clark, 1999) and this product has been used in recent experiments that have demonstrated its protective and physiological effects (Johnson et al., 2009; Loeb et al., 2011; Roberge et al., 2010a). Based upon measurements taken in our NPPTL laboratory, the study SM weighs 4.7 g, has a breathing resistance of 3.9 mm (0.4) H_2O pressure (measured at 85 liters-per-minute of continuous airflow with a TSI 8130 Filter Tester [TSI Incorporated, Shoreview, MN]), and a surface area of 295.50 cm^2. The SM is held in place by two tie straps that are secured by the wearer at the back of the neck and occiput (crown) of the head, as per manufacturer's instructions. The nose bar of the SM is pliable to enable it to conform to the nasal bridge. All subjects underwent respiratory fit testing, though it was anticipated that the SMs would not pass respiratory protection programs (OSHA, 1998) because of their loose fit and the fact that they are not considered respiratory protective equipment. Study SMs were not pre-conditioned, and testing was carried out in a physiology laboratory during a three-month period of winter in the northern hemisphere. Laboratory mean ambient environmental conditions during the study period were: temperature 21.47 °C (0.97), RH 23.10% (7.87), and barometric pressure 737.75 mm (5.48) Hg pressure (corrected for standard temperature and pressure).

2.4. Instrumentation

Core temperature (T_{core}) was monitored by an ingestible, 8.7 mm diameter × 23 mm length biocompatible Jonah® temperature capsule (Philips Respironics, Bend, OR) that was swallowed with 50–100 ml of tepid water. Dermal temperatures (right buccal region [T_{cheek}], left perioral region under the SM [T_{cheekM}], left epigastric abdominal region [$T_{abdomen}$]) were monitored with Vital Sense® hypoallergenic, 57.2 mm diameter × 5.3 mm thickness water-resistant, disposable wireless dermal sensors (Philips Respironics). Both the core temperature capsule and dermal sensor have a manufacturer-stated accuracy of ±0.1 °C at 32–42 °C that has been verified in physiological studies (Savastano et al., 2009; McKenzie and Osgood, 2004). The T_{cheek} sensor was not covered by the SM, whereas a portion of the T_{cheekM} sensor's adhesive backing was removed to decrease the sensor's diameter and ensure complete coverage by the SM. T_{core} and dermal temperatures are measured every 15 s and reported as 1 min averages real time on a battery-powered portable data logger/monitor carried on a belt worn by the test subject.

SM deadspace temperature (T_{micro}) and relative humidity (RH_{micro}) were measured every 20 s (user defined sampling rate) by an I-Button® semiconductor temperature and humidity sensor (I-Button, Dallas, TX) that incorporates a real time clock, memory, and 3 V lithium battery encased in a small (16 mm × 6 mm) stainless steel can (temperature range, −40 to 85 °C) and has been previously utilized to evaluate PPE (Davis and Shaw, 2011; Roberge et al., 2012). The I-Button® was adhesively affixed to the right perioral peripheral region of the inner surface of the SM. Prior to the study, pilot I-Button® sensor T_{micro} and RH_{micro} data were compared over 1 h with concurrent data from a DewMaster® chilled mirror hygrometer (EdgeTech, Marlborough, MA) that was calibrated to standards traceable to the National Institute of Standards and Technology and a strong correlation was noted (r = 0.99). The heart rate (HR) and the derived respiratory rate (RR) were reported every 15 s using a Vitalsense® XHR wireless sensor (Phillips Respironics) that uses two standard electrocardiographic (ECG) pads attached to the chest wall. The basis for the derived RR rests upon HR increases during inhalation and decreases during exhalation that result in oscillations of ECG R-Rwave interval series corresponding to breathing activity (Sobron et al., 2010). The XHR determines the RR through signal processing of the relationship of respiration-induced variations of the ECG R-wave amplitude. Good correlations are achieved between ECG-derived RR and standard methods of RR determinations (Cysarz et al., 2008). XHR manufacturer's specifications indicate a HR range of 16–240 beats-per-minute, HR resolution of ±1 beat-per-minute, HR accuracy of >±10% or 5 beats-per-minute, and RR of 2 respirations-per-minute ≤¼ HR, and has been reported to provide reliable data even in harsh environments (Wagner, 2011).

A heated (42 °C), combination transcutaneous carbon dioxide ($tcPCO_2$) sensor/pulse oximeter (Tosca 500 Monitor, Radiometer, Copenhagen, DK) that attaches to the earlobe with a disposable plastic clip with adhesive backing was placed on the left ear lobe and linked to a viewing monitor with continuous readouts of $tcPCO_2$, oxygen saturation (SpO_2) and HR. The Tosca 500 employs a Severinghaus-type sensor that potentiometrically measures the partial pressure of carbon dioxide (PCO_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 PCO_2 change (Roberge et al., 2010b). The sensor automatically calibrates over a 10 min period at the onset of use and thereafter every 4 h using an attached CO_2 canister. The lag time for $tcPCO_2$ measurements is typically <1 min (Eberhard, 2007). The pulse oximeter component records and downloads SpO_2 and HR data at ~3 s intervals continuously and has a rated accuracy of ±2%.

2.5. Protocol

Subjects were attired in tee-shirts, athletic shorts or sports pants, and athletic shoes and walked initially on a treadmill at a low-moderate work rate (5.6 km/h; 0° inclination) continuously for a period of 1 h without a SM (controls) followed by the same activity for 1 h while wearing a SM (trials). Controls and trials were not randomized and subjects had a minimum respite of 30 min in the study laboratory between these activities. During treadmill exercise, subject perceptions of exertion (RPE) were assessed every 5 min using the Borg scale that has ranges of 6–12 ("no exertion" to "fairly light exertion"), 13–16 ("somewhat hard" to "hard"), and 17–20 ("very hard" to "very, very hard") (Borg, 1982). Heat perceptions (RHP) were assessed every 5 min with the Frank scale that has ranges from 0 to 4 ("the coldest you have ever been" to "slightly cold"), 5 ("neither hot nor cold"), and 6–10 ("slightly hot" to "the hottest you have ever been") (Frank et al., 1999). At the end of the trials, subjects filled out a questionnaire detailing any complaints or comments regarding the SM. Before and after the trials, SMs were weighed on an ACCU-6201 calibrated analytical balance (Fisher Scientific, Waltham, MA) to determine the quantity of moisture retention.

2.6. Data analysis

Following the completion of controls and SM trials, seven measured dependent variables (T_{core}, T_{cheek}, $T_{abdomen}$, HR, RR, RPE, RHP) were first calculated as mean and standard deviations in 5 min time intervals and paired for each individual subject ($n = 20$). A variable with a significant number of missing values within a subject, thus not being paired for the two trials, was removed from statistical analysis. The seven dependent variables were analyzed by a two-way repeated measures ANOVA (SM × Time) to determine main effect and interactions with the Greenhouse-Geisser correction for sphericity for designation of statistical significance. For a significant F statistic obtained from the repeated measures, post hoc pair-wise comparison was performed with Bonferroni adjustment accompanied with a paired t-test. Additionally, any variable that showed a significant difference in baseline (0 min) measurement between the two trials was further analyzed by a delta analysis (total change from baseline: 0 min, to end-point: 60 min). The three deadspace variables that were only measured in SM trials (T_{micro}, RH_{micro}, T_{cheekM}) were analyzed by one-way repeated measures ANOVA (Time) with the same procedures described above. Pearson's correlation (one-tailed) was also performed to examine the relationship between RH_{micro} and T_{micro} on T_{cheekM}. Differences in 1 h mean SpO_2 and $tcPCO_2$ values between controls and trials were analyzed by paired t-tests. Alpha level was maintained at 0.05 for all comparisons, and all analyses were performed using a statistical software package (SPSS v.18, IBM, Somers, NY).

3. Results

All subjects completed control and SM trials (total, 40 tests). The mean elapsed time from core temperature capsule ingestion to the start of control data collection was 123.9 min (62.9), and 327.0 min (159.3) during trials. Post-test mean increase in SM weight was 0.12 g (0.19).

The mean values at five minute intervals for seven measured variables of controls and trials are displayed in Table 1. Time had a significant effect ($p < 0.001$) on these measured variables. Mean 1 h values for controls vs trials study variables, respectively, were: T_{core} 37.56 °C vs 37.64 °C ($p = 0.15$), T_{cheek} 32.44 °C vs 32.04 °C ($p = 0.03$), $T_{abdomen}$ 32.82 °C vs 33.12 °C ($p = 0.22$), HR 110.8 vs 120.3 ($p < 0.001$), RR 21.7 vs 23.3 ($p = 0.02$), RPE 9.6 vs 10.2 ($p = 0.10$), and RHP 5.72 vs 5.80 ($p = 0.57$) (Table 1, Fig. 1). For SM deadspace parameters, time had a significant effect ($p < 0.001$) on 1 h T_{micro} (mean increase of 1.60 °C), RH_{micro} (mean increase of 38.3%) and T_{cheekM} (mean increase of 1.76 °C) (Table 2, Fig. 2). Pearson's correlation coefficients for the effect of the RH_{micro} and T_{micro} on T_{cheekM} were, respectively, 0.988 and 0.932 ($p = 0.01$). The controls and trials 1 h mean SpO_2 values were 97.62% and 97.54%, respectively ($p = 0.83$), and the corresponding $tcPCO_2$ values were 39.31 and 41.48 mm Hg ($p = 0.0006$). The mean quantitative fit factor (ratio of ambient particles outside the SM to particles in the breathing zone of the SM) was 3.6 (OSHA minimum passing score for a FFR is 100 [OSHA, 1998]) and no subject passed a fit test. Complaints of facial warmth constituted the single most frequent complaint (52%) regarding SMs (Fig. 3).

4. Discussion

Recent findings have suggested that SMs are not inferior to FFRs in terms of protection from laboratory confirmed influenza infection rates and in reducing the spread of influenza viruses (Loeb et al., 2009; Johnson et al., 2009; Ang et al., 2010). Although still controversial based on the aerosol transmission capability of influenza virus (Tellier, 2009), these results imply that comfort, rather than protection, may become a prominent feature of the selection of PFs (Johnson et al., 2009). Intolerance to PFs is related to discomfort from the various physiological and psychological stressors placed on the wearer. Intolerance to SMs may lead to noncompliance, resulting in increased exposure to body fluids and airborne pathogenic organisms. In order to address the issue of SM intolerance, reliable data regarding SM-related stressors are needed. Although thermal issues are central to many complaints regarding intolerance to PFs, including SMs (Hayashi and Tokura, 2004; Li et al., 2005; Guo et al., 2008; Baig et al., 2010), our study results would indicate that the thermal impact of a SM on T_{core} is minimal over the course of 1 h of continuous wear at a low-moderate work rate typical of most modern workers (Meyer et al., 1997; Harber et al., 2009). The mean increase in T_{core} over controls when wearing a SM, measured from intestinal temperature, was only 0.08 °C, similar to the 0.07 °C increase in aural (tympanic) temperature of healthcare workers wearing SMs for 30 min noted by Yip et al. (2005). PF-associated increases in T_{core} relate to the additional energy expenditure to overcome breathing resistance of the PF, interference with respiratory heat exchange, and inhibition of convective and evaporative heat release mechanisms of the skin that is covered by the PF (Roberge et al., 2011). In the case of the SM utilized in the current study, the breathing resistance of the filter is quite low (3.9 mm ± 0.4 H_2O pressure) and the fit was loose to the face (as indicated by the very low mean quantitative fit factor [i.e., 3.6] achieved), so that the breathing effort should not have been excessive compared with other PFs. However, the barrier effect of the SM traps warm exhaled air and impedes convection and evaporation of some facial skin that, together with facial sweat accumulation under the SM, creates T_{micro} and RH_{micro} levels that increased the T_{cheekM} by 1.76 °C. This is not surprising when one considers that, at the 60 min values for T_{micro} and RH_{micro} of 32.74 °C (1.20) and 91.49% (8.88), respectively, the SM deadspace has an apparent heat index of 52.9 °C (National Oceanographic and Atmospheric Administration, 2007), which represents a composite of the humidity and temperature effects that is the facial temperature sensed by the SM wearer (Enerson et al., 1967). The impact of the SM microenvironment heat index upon the wearer is verified by the proportion of subjects (52%) who offered complaints of facial warmth (Fig. 3) and the strong correlation coefficients noted for RH_{micro} (0.988) and T_{micro} (0.932) on T_{cheekM} ($p = 0.01$). The mean 1 h data for T_{micro} (32.44 °C), RH_{micro} (78.86%) and T_{cheekM} (33.16 °C) differ somewhat from a prior study (Enerson et al., 1967) with values, respectively, of 31.04 °C, 90.26%, and 31.95 °C (skin temperature tip of nose) and 34.70 °C (skin temperature at chin). However, that investigation studied six different SMs, utilized only 2 subjects, was not associated with exercise, and was limited to 15 min for each session. Our RH_{micro} is comparable with that of Li et al. (2005), but our T_{micro} (32.74 ± 0.44) is somewhat less than the ~34 °C they noted. However, their subjects exercised in hotter and more humid ambient conditions (temperature 25 °C, RH 70%) than the current study (21.47 °C, 23.10%). The significantly lower temperature of T_{cheek} during trials compared with controls ($p = 0.03$) in the current study may relate to the cooling effects of air escaping from the periphery of the SM, a phenomenon termed "venting" (Belkin, 1996).

Wearing an SM resulted in a mean HR over 1 h of 120.3 beats-per-minute, an increase of 9.4 beats-per-minute over control values ($p < 0.001$) (Fig. 1). Increased warmth and exertion would be expected to increase the HR, but T_{core} was only minimally increased during trials (0.08 °C) and was not associated with an increased perception of exertion (i.e., RPE). Although RPE data were not statistically significant when comparing controls with trials, they did display a trend toward significance ($p = 0.10$) that hypothetically, with greater subject numbers or an extended period of use, might have resulted in a significant effect on the perception of exertion

Table 1
Measurement variables comparing control (no surgical mask) and surgical mask trials.

Trial	Time (min)	Measurement variables						
		T_{core}	T_{cheek}	$T_{abdomen}$	HR	RR	RPE	RHP
Control	0	37.25 (0.26)	31.85 (0.93)	32.04 (1.48)	81.4 (11.6)	16.7 (3.6)	8.2 (2.3)	4.3 (0.7)
	5	37.24 (0.26)	31.97 (0.74)	32.08 (1.46)	103.3 (12.7)*	20.7 (3.7)*	8.3 (1.9)	4.7 (0.6)*
	10	37.32 (0.28)*	32.12 (0.72)*	32.33 (1.40)*	109.4 (12.7)*	20.6 (3.1)	8.6 (1.8)*	5.0 (0.6)*
	15	37.44 (0.30)*	32.24 (0.76)*	32.58 (1.38)*	110.9 (10.6)	21.8 (3.4)*	9.1 (1.7)*	5.4 (0.5)*
	20	37.52 (0.29)*	32.36 (0.82)*	32.79 (1.35)*	111.4 (10.6)	21.9 (3.3)	9.2 (1.6)	5.7 (0.7)*
	25	37.59 (0.29)*	32.44 (0.86)*	32.94 (1.29)*	114.3 (12.5)	21.7 (3.2)	9.5 (1.6)	5.7 (0.6)
	30	37.63 (0.25)*	32.56 (0.92)*	33.09 (1.23)*	115.4 (11.9)	21.9 (3.3)	9.8 (1.7)*	6.0 (0.6)*
	35	37.67 (0.22)*	32.63 (0.98)	33.17 (1.17)	114.9 (11.2)	23.1 (3.5)	10.0 (1.6)	6.1 (0.6)
	40	37.71 (0.22)*	32.65 (0.97)	33.11 (1.13)	117.5 (13.8)	22.2 (2.3)	10.4 (1.6)*	6.2 (0.6)
	45	37.73 (0.23)	32.73 (0.93)	33.11 (1.07)	114.7 (12.3)	22.9 (3.1)	10.5 (1.7)	6.3 (0.7)
	50	37.74 (0.27)	32.71 (0.93)	33.12 (0.98)	115.4 (12.6)	22.6 (3.5)	10.6 (1.8)	6.3 (0.8)
	55	37.76 (0.26)	32.75 (0.92)	33.15 (0.96)	116.0 (14.6)	23.0 (2.8)	10.7 (1.8)	6.5 (0.8)
	60	37.77 (0.25)‡	32.77 (0.92)‡	33.20 (0.95)‡	116.9 (15.6)‡	23.7 (2.7)‡	10.6 (1.8)‡	6.2 (0.8)‡
Surgical mask	0	37.17 (0.42)	31.29 (1.33)	32.60 (0.94)	83.9 (13.1)	16.9 (2.4)	8.3 (1.7)	4.4 (0.6)
	5	37.26 (0.35)*	31.54 (1.07)*	32.49 (1.01)	115.9 (10.6)*	21.8 (3.5)*	8.7 (1.8)*	4.9 (0.6)*
	10	37.39 (0.31)*	31.69 (1.07)*	32.68 (0.92)*	121.0 (12.3)*	22.9 (3.1)	9.3 (1.7)*	5.2 (0.7)*
	15	37.52 (0.29)*	31.82 (1.10)*	32.85 (0.92)*	122.6 (12.6)	23.9 (3.6)	9.4 (1.7)	5.4 (0.7)*
	20	37.59 (0.24)*	31.95 (1.08)*	33.08 (0.90)*	121.3 (13.7)	22.9 (4.3)	9.8 (1.6)*	5.6 (0.8)*
	25	37.69 (0.26)*	32.03 (1.00)	33.28 (0.85)*	122.3 (15.1)	23.4 (4.0)	10.3 (1.7)*	5.9 (0.8)*
	30	37.73 (0.25)*	32.14 (0.96)	33.36 (0.85)*	123.2 (16.8)	24.5 (3.4)*	10.4 (1.7)	6.0 (0.8)
	35	37.76 (0.25)*	32.25 (0.99)	33.42 (0.86)	126.4 (14.0)	24.8 (4.1)	10.7 (1.9)	6.2 (0.9)*
	40	37.78 (0.27)	32.21 (1.04)	33.39 (0.85)	123.9 (15.9)	24.3 (3.9)	10.8 (1.6)	6.2 (0.9)
	45	37.83 (0.27)*	32.28 (1.00)	33.36 (0.88)	125.1 (16.8)	24.0 (4.1)	11.2 (1.8)*	6.4 (0.8)*
	50	37.86 (0.28)*	32.41 (0.98)*	33.37 (0.87)	123.7 (17.2)	24.3 (3.5)	11.2 (1.8)	6.4 (0.7)
	55	37.88 (0.27)*	32.48 (0.98)*	33.37 (0.82)	127.3 (17.0)	24.5 (3.6)	11.3 (1.8)	6.5 (0.8)
	60	37.90 (0.27)*‡	32.51 (0.98)‡	33.40 (0.81)‡	128.3 (15.6)‡	24.7 (3.7)‡	11.2 (1.7)‡	6.3 (0.8)‡

Values are presented as mean (SD). T_{core}: core body temperature (°C) (n = 19), T_{cheek}: cheek temperature (°C) (n = 20), $T_{abdomen}$: abdomen temperature (n = 20), HR: heart rate (beats min^{-1}) (n = 20), RR: respiratory rate (breaths min^{-1}) (n = 15), RPE: ratings of perceived exertion (620) (n = 20), RHP: ratings of heat perception (0–10) (n = 20).
* Significantly different from the previous measurement.
‡ Significantly different between baseline (0 min) and trial end-point (60 min).

that could influence HR. Li et al. (2005) reported HR that ranged from 70 to ~92 for subjects exercising while wearing SM, but the exercise regimen was different from the current study in that it was a staggered trial (three 20 min exercise periods interspersed with 10 min rest periods), so that comparisons with our data are not straightforward. Beder et al. (2008) reported an average HR of 91 in surgeons performing surgery for up to a 1 h period, an increase of 10% over control values (not operating and not wearing a SM), similar to the 8% increase noted in the current study. The mean HR found in the current study is somewhat comparable with that of 106.4 reported for class N95 FFRs (Roberge et al., 2010b) over 1 h of exercise, when the lower work rate (4.02 km/h) of the latter study is factored in to the comparison. This suggests equivalent HR responses to SMs and N95 FFRs over 1 h at low-moderate work rates, but this supposition requires more study.

The increase in RR associated with SM use is related to having to overcome the resistance of the filtration media, though it is recognized that filtration varies widely among SMs (Rengasamy et al., 2009). The mean RR over 1 h was 23.3 breaths-per-minute in the current study, reflecting an increase of 1.6 breaths-per-minute over controls (Fig. 1). Although this is statistically significant (p = 0.02), its practical significance is questionable in healthy persons. By comparison, use of N95 FFRs for 1 h while treadmill exercising at a 28% lower work rate (4.02 km/h; 0° inclination) was associated with a 13% greater RR of 26.6 breaths-per-minute (Roberge et al., 2010b) and likely reflects the greater degree of breathing resistance

Table 2
Mean surgical mask deadspace parameters measured every 5 min. over 1 h.

Trial	Time (min)	Measurement variables		
		T_{micro}	RH_{micro}	T_{cheekM}
Surgical mask	0	31.14 (1.14)	53.19 (17.66)	31.94 (1.10)
	5	31.98 (1.34)*	59.22 (15.52)*	32.44 (1.00)*
	10	32.25 (1.30)*	65.00 (14.88)*	32.74 (1.00)*
	15	32.49 (1.33)*	71.10 (13.11)*	32.92 (0.98)*
	20	32.58 (1.28)	78.08 (12.24)*	33.13 (0.96)*
	25	32.67 (1.34)	81.85 (12.06)*	33.28 (0.93)*
	30	32.68 (1.28)	84.35 (11.67)*	33.41 (0.96)*
	35	32.73 (1.26)	85.55 (11.62)	33.48 (0.94)*
	40	32.61 (1.38)	87.43 (11.14)*	33.44 (0.94)
	45	32.64 (1.41)	88.63 (10.89)*	33.47 (0.95)
	50	32.61 (1.33)	89.34 (10.62)*	33.58 (0.91)*
	55	32.71 (1.23)*	89.99 (10.37)	33.67 (0.88)*
	60	32.74 (1.20)‡	91.49 (8.88)‡	33.70 (0.88)‡

Values are presented as mean (SD).
T_{micro}: microclimate temperature (°C) (n = 20), RH_{micro} microclimate relative humidity (%) (n = 20), T_{cheekM}: face temperature inside surgical mask (°C) (n = 18).
* Significantly different from the previous measurement.
‡ Significantly different between baseline (0 min) and trial end-point (60 min).

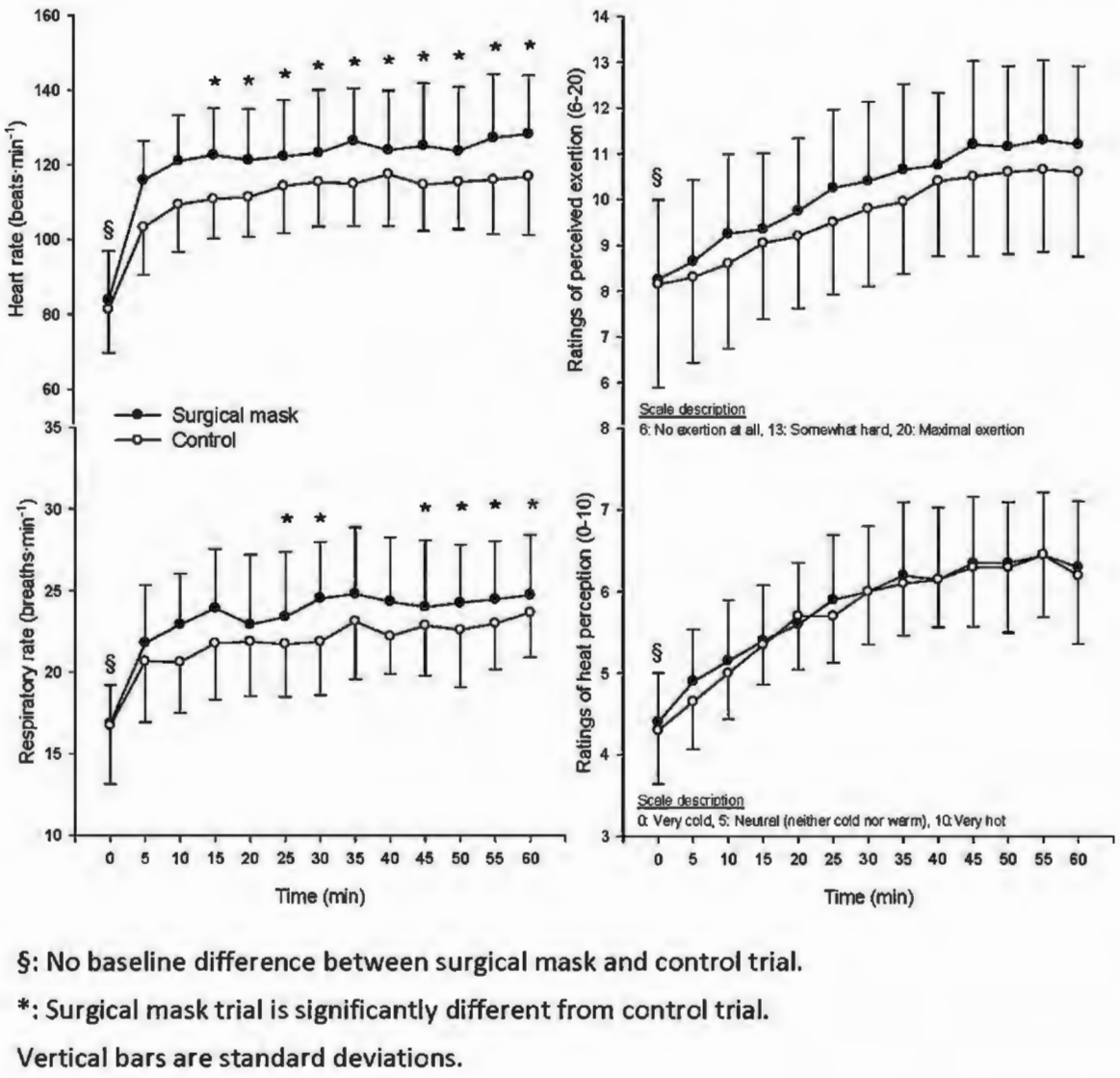

Fig. 1. Comparison of control (no surgical mask) and surgical mask responses for heart rate, respiratory rate, perceived exertion, and heat perception over the course of 1 h.

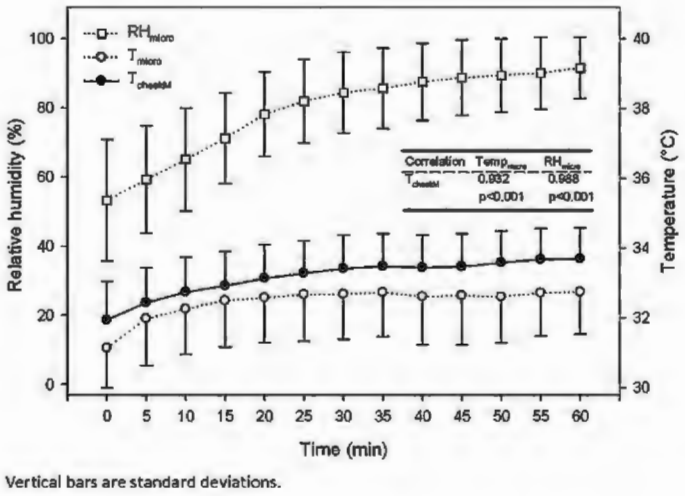

Fig. 2. Surgical mask deadspace air temperature, relative humidity and skin temperature over 1 h.

Fig. 3. Distribution of complaints offered by 20 subjects wearing a surgical mask for 1 h.

associated with FFRs. Despite decreased breathing resistance compared with FFRs, difficulty with respiration when wearing a SM was reported by 12% of children and 38% of adults in one recent study (Canini et al., 2010). Li et al. (2005) reported a significant association of the perception of increased breathing resistance for both SMs and FFRs. It has been reported that PF-associated increases in RH_{micro} can increase breathing resistance or alter the breathing pattern (Gwosdow et al., 1989), and this may be operant in those instances in which SM wearers report difficulty breathing. Another possible reason for the increased RR in the current study may be related to the proportion of subject complaints (11%) with respect to the SM sticking to the face during inhalation, with resultant increased breathing effort (Fig. 3). Further, the impact of psychological stressors (e.g., anxiety, claustrophobia, etc.) on the RR of some SM wearers cannot be overlooked (Wu et al., 2011), though this was not overtly evident during the current study. Recent work indicating that unpleasant sensory experiences may be translated into emotional responses (Williams et al., 2010), suggest that the unpleasantness of having a SM on one's face may result in a sensation of breathlessness and associated increase in the RR. The use of a SM did not result in any significant change in SpO_2, a finding in agreement with studies investigating surgical masks, N95 FFR, and N95 FFR with a surgical mask overlay (Beder et al., 2008; Roberge et al., 2010a,b). The SM was associated with a significant mean increase in $tcPCO_2$ levels ($p = 0.0006$), but quantitatively was only 2.17 mm Hg over the course of 1 h and is similar to prior studies of PF (Roberge et al., 2010a,b).

Subjective perceptions of SM use have rarely been studied. Our data did not demonstrate any significant difference in RPE ($p = 0.10$) or RHP ($p = 0.57$) between controls and trials (Fig. 1). Subjects wearing a SM indicated that heat perception ranged between neutral and lightly hot, and that perceived exertion ranged between very, very light and fairly light, indicating that the use of a SM under the conditions of the study was not subjectively overly discomforting. Using a scale of 0–3 ("not at all"), 3–7 ("mildly"), and 8–10 ("strongly") in the subjective evaluation of SMs, Li et al. (2005) found scores of 1–4 for humidity, hotness, and breathing resistance that share some concordance with our data. Guo et al. (2009), testing healthcare workers performing usual routines over a 7 h period while wearing protective ensembles (surgical gowns, aprons) with different PFs, evaluated subjective perceptions using a scale of 0–7 ("not at all" to "very strong"). Perceptions for hotness and wetness within SMs were very slight to slight, and for N95 FFRs were somewhat slight to somewhat strong for hotness and somewhat slight to somewhat strong for wetness, differences that were statistically significant ($p < 0.01$). By way of further comparison, utilizing a RHP scale of 1–5 ("neutral", "slightly warm", "warm", "hot", "very hot") and RPE scale of 0–1 ("extremely easy"), 2–3 ("easy"), 4–5 ("somewhat easy"), 6–7 ("somewhat hard"), 8–9 ("hard"), and 10 ("extremely hard") during 1 h of treadmill testing while wearing N95 FFRs, Roberge et al. (2010b) reported mean RPH and RPE scores of 1.67 and 1.11, respectively, that correlate with neutral to slightly warm and extremely easy to easy exertion, but the work rate (4.02 km/h, 0° inclination) was less than the current study.

The SM weight gain after 1 h of use was minimal (0.12 ± 0.19 g) and reflects the hydrophobic nature of polypropylene fibers that makes up the majority of the SM material. The minimal weight gain is similar to previous findings for N95 FFR (Roberge et al., 2010b). Also, the loose fit of the SM allows passage of moisture-laden air out from the sides, thereby exposing the SM to less exhaled moisture.

Taken in the aggregate, the physiological responses and subjective perceptions of discomfort and exertion experienced by healthy individuals when wearing a SM over a 1 h period at a low-moderate work rate are minimal. Even those parameters that displayed statistically significant differences with controls (i.e., T_{cheek}, RR, HR) would have minimal clinical significance. This is perhaps not surprising given that the use of PFs with greater breathing resistance than SMs (i.e., negative pressure air-purifying respirator, FFR) in simulated work conditions has been shown to be well tolerated by individuals with controlled respiratory disorders (Harber et al., 2009). The discomfort associated with SM wear is thus not a factor of associated exertion, but rather one of SM-related discomfort (Shenal et al., 2012). This discomfort may relate to neurological reactions (e.g., increased afferent impulses from the highly thermosensitive area of the face covered by the SM, brain warming due to the increased temperature of the inspired air when wearing PFs) or associated psychological phenomena (e.g., anxiety, claustrophobia, affective responses to perceived breathing difficulty) (Roberge et al., 2011; Williams et al., 2010), but these assumptions will require more investigation.

Limitations of the current study include the relatively small number of subjects ($n = 20$) studied and the fact that it is a laboratory study rather than a workplace study. However, laboratory studies may actually represent the upper bounds of physiological impact compared with field studies (Harber et al., 2009). Also, we studied only one style (flat fold) of a SM from one manufacturer and cannot therefore comment on other models and styles (e.g., duckbill, cup-shaped, etc.). We studied a SM with two ties that are secured by the wearer, but other SM models offer different tethering devices (e.g., ear loops, elastic bands, etc.) that may affect fit to the face and, therefore, performance. For example, SMs with two tie straps have been shown to have better fit factors than SMs with a single elasticized strap (Gawn et al., 2008). Our study trials were for 1 h, but some individuals (e.g., operating room staff, triage personnel, etc.) may wear SMs for protracted periods of time that may result in a greater thermal burden and may increase breathing resistance if the SM gets excessively moist. Almost half of healthcare workers were unable to tolerate a SM for an entire eight hour shift (Shenal et al., 2012). However, many healthcare workers perform multiple donning of SMs for much shorter periods of time during a typical work shift. The ambient conditions of the study were temperate and we cannot comment on the use of SMs in more extreme environmental conditions. Lastly, all of our subjects were young, healthy adults so that we cannot comment on the impact of SMs on subjects with underlying cardiopulmonary disorders who might need to wear SMs (e.g., infected patients during ambulance transport, etc.), though recent investigation has shown that individuals with controlled pulmonary disorders (e.g., asthma, mild chronic obstructive pulmonary disease, chronic rhinitis) can tolerate the more restrictive FFRs and elastomeric air-purifying respirators (Harber et al., 2010).

5. Conclusions

Our study demonstrated that, over the course of 1 h of wearing a SM at a low-moderate work rate, mild increases in physiological responses (HR, RR, $tcPCO_2$) occur that would be of no clinical significance in healthy persons and that were not perceived subjectively as being associated with discomfort or exertion. The thermal burden of a SM on the wearer is not excessive, with the exception of facial skin covered by the SM, and SaO_2 is not negatively impacted. Intolerance to wearing a SM is not likely related to an increased physiological burden, but may reflect SM-related neurological or psychological effects.

Disclaimer

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

The authors report no financial conflicts. All funding for the study came from internal operating funds of the National Personal Protective Technology Laboratory.

Acknowledgements

The authors thank Jeffrey Powell, MS and Dr. Aitor Coca for their assistance with equipment issues, and Dr. Ronald Shaffer, Dr. Ziqing Zhuang, Dr. William King, and Jay Parker, MS for their manuscript reviews and suggestions.

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