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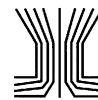
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Surgical smoke simulation study: Physical characterization and respiratory protection

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ABSTRACT

Exposure of operating room (OR) personnel to surgical smoke, a unique aerosol generated from the common use of electrocautery during surgical procedures, is an increasing health risk concern. The main objective of this simulation study was to characterize the surgical smoke exposure in terms of the particle number concentration and size distribution in a human breathing zone. Additionally, the performance of respiratory protective devices designed for ORs was examined using two commercially available N95 facepiece filtering respirators (FFRs) as well as the same FFRs modified with new faceseal technology. The tests were conducted in an OR-simulating exposure chamber with the surgical smoke generated by electrocautery equipment applied to animal tissue and measured in the breathing zone with four aerosol spectrometers. The simulated workplace protection factor of each tested respirator was determined for ten subjects by measuring the total aerosol concentrations inside and outside of a respirator. The peak of the particle size distribution was in a range of 60–150 nm. The concentration of particles generated during the simulated surgical procedure significantly exceeded the background concentration under all tested air exchange conditions. The data suggest that wearing N95 filtering facepiece respirators significantly decreased the human exposure to surgical smoke. The new faceseal technology provided significantly higher respiratory protection than the commercial N95 FFRs.

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Introduction

Destruction of tissues by thermal energy during surgical procedures, most commonly electrocautery, generates surgical smoke in operating rooms (ORs). The smoke released from the surgical procedures has been shown to contain chemicals, cytotoxic components, carbon monoxide, non-viable cellular material, viable bacteria and viruses, and HIV DNA (Baggish et al. 1988; Baggish and Elbakry 1987; Barrett and Garber 2003; Bröske-Hohlfeld et al. 2008; Capizzi et al. 1998; Fletcher et al. 1999; Hensman et al. 1998; Moot et al. 2007; Sagar et al. 1996; Ulmer 2008; Wu et al. 1997). Additionally, the mutagenicity of samples captured from surgical smoke was found to be comparable to the level generated by smoking multiple unfiltered cigarettes in the same room (Hill et al. 2012).

The surgical smoke particles released from the patient's tissue can easily reach the breathing zone of the surgeon and assistants, who are closest to the surgical field. According to a recent healthcare worker survey,

99% of the respondents worked within 5 feet of the source of surgical smoke formed during electrosurgery (Steege et al. 2016). There has been a growing concern about the potential health effects associated with daily exposure to surgical smoke in ORs. These include, but are not limited to, emphysema, asthma, chronic bronchitis, anemia, and leukemia (Alp et al. 2006). The Occupational Safety and Health Administration (OSHA) has estimated that 500,000 healthcare workers are exposed to surgical smoke annually in the USA (OSHA 2016). However, there is a paucity of clinical retrospective studies, and no prospective studies, as to the effects of surgical smoke on OR healthcare workers.

Among very few published studies in this field, a pilot investigation by Lopez et al. (2015) established a method for identifying operational parameters that affect the size specific mass emission rates for particulate matter generated by a simulated laser medical procedure. While this effort produced important preliminary data about aerosol generation, the findings were limited and reflected

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only this clinical procedure and only with respect to laser-generated aerosols (versus aerosols generated with electrocautery which is the most common energy source used during surgical dissection).

To our knowledge, OSHA has not published any regulations or specific standards addressing inhalation hazards related to smoke from surgical procedures; however, it does have regulations and standards for some substances that are found in surgical smoke. There is an apparent lack of consensus and regulations between surgical and occupational health organizations. Recommendations for using personal protective equipment (PPE) and local exhaust ventilation (LEV) have been introduced by OSHA, the National Institute for Occupational Safety and Health (NIOSH), and the Association of Perioperative Registered Nurses (AORN) to limit exposure to surgical smoke particles in ORs (OSHA 2016; NIOSH 1996; Spruce and Braswell 2012). The use of NIOSH-certified N95 filtering facepiece respirators (FFRs) has been recommended only in surgery performed on tissues containing human papilloma virus (HPV). Otherwise, much less efficient surgical masks (SMs), which are not subject to NIOSH certification, are usually deployed. According to a survey by Steege et al. (2016), only 14% of those exposed during electrosurgery and 47% of those exposed during laser surgery always used LEV, and approximately 50% of the respondents indicated that wearing respirators was not part of their protocol in ORs. Finally, of those who reported wearing certified respirators, only two-thirds of the participants quoted in the survey stated that their respirators had been fit-tested.

Inhalation exposure to surgical smoke in ORs remains insufficiently evaluated. Very limited knowledge has been acquired regarding the particle size distribution of OR-generated surgical smoke, which makes the exposure and dose assessment difficult. Pilot studies have been conducted to evaluate the efficiency of some traditional SMs and FFRs against surgical smoke in OR-simulated

environments. It was reported that FFRs, such as N95 and N100, offer higher levels of protection against surgical smoke as compared to SM (Gao et al. 2016). It was also found that a newly developed faceséal concept (based on replacing the original faceséal with one incorporating novel design features) has great potential for improving the performance of N100 FFRs (Gao et al. 2016; Koehler et al. 2014). There is a need for a follow-up investigation involving N95 FFRs that are used in ORs.

The main objective of this simulation study was to assess surgical smoke exposure of unprotected healthcare workers by measuring the number concentration and particle size distribution of smoke aerosol in the human breathing zone. Additionally, we compared the performance of existing and new N95 FFRs used/developed for ORs against surgical smoke.

Materials and methods

Generation of surgical smoke in the OR-simulation facility

This study was conducted in a simulated OR facility that included a 24 m³ exposure chamber. The chamber was equipped with an adjustable ventilation system to establish and maintain desired air exchange rate. A special aerosol sampling system was built for measuring surgical smoke by using multiple aerosol instruments. It consisted of an inlet, a mixing chamber, an air dilution module equipped with a fan and a high-efficiency particulate air (HEPA) filter, a set of sampling ports connected to individual aerosol spectrometers, and the main fan (Figure 1).

The surgical smoke was generated in the chamber as the study subject performed electrocautery dissection of lamb muscle tissue on a surgical table of 1 m high (typical for an OR), thus simulating a conventional surgical procedure. A piece of the tissue (fresh, kept at ambient

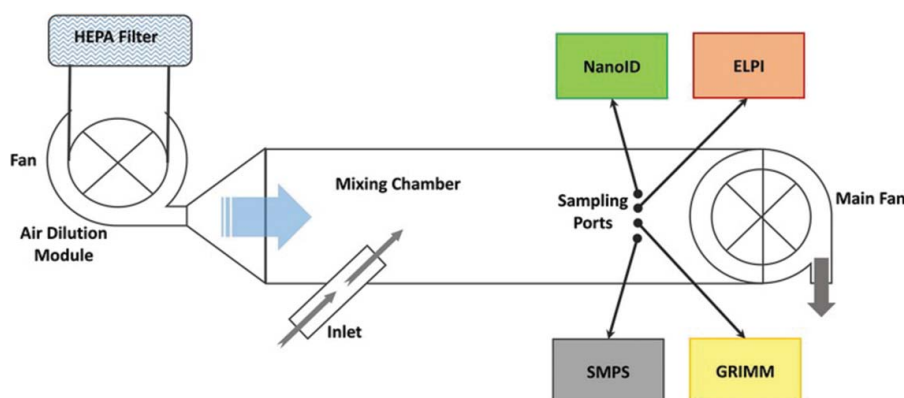


Figure 1. Sampling system for the surgical smoke aerosol characterization.

temperature) was placed on a grounded plate attached to an electrosurgical generator (ValleyLab Force FX, Covidien, Boulder, CO, USA); a standard electrosurgical pencil (ValleyLab E2516, Covidien, Boulder, CO, USA) was utilized. The generator was set to a power of 40 W for cutting and coagulation option using a blend mode, which is a commonly used setting.

The surgical smoke forms as the electrosurgical pencil is applied to the tissue, creating plumes that propagate further from the source. This leads to a high spatial and temporary variability of the aerosol concentration and particle size distribution in the breathing zone, which presents a challenge when using a scanning aerosol spectrometer. The issue becomes even more complex when multiple aerosol spectrometers with different recording time intervals and different flow rates are deployed operating in parallel. A single aerosol sampling inlet with the mixing chamber downstream (Figure 1), as well as a relatively long sampling time (10 min), allowed for minimizing the above-described variability associated with heterogeneity of the smoke aerosol generation.

Aerosol characterization in the breathing zone

Four particle size spectrometers were chosen to characterize the concentration and particle size distribution of surgical smoke in the breathing zone of a subject, namely, NanoID, ELPI, SMPS, and Grimm NanoCheck-Carrier. The manufacturer information, operating principles and technical specification details for these instruments are presented in Table 1.

Each instrument was connected to a specific sampling port downstream of the mixing chamber as shown in Figure 1. In the preliminary testing – as a part of development and validation of the study design – rotation of sampling ports was implemented; it was found that the location did not affect the results. The particle size distribution was measured in three replicates with each of the

four aerosol spectrometers. From three replicate measurements, the geometric mean (GM) and geometric standard deviation (GSD) were calculated for each particle size fraction, and the resulting “mean” distribution from the three replicates was determined and used for further comparisons that aimed at examining the effect of a measurement device and air exchange rates. The aerosol measurement data were used to characterize the surgical smoke aerosol.

Air exchange rate in the exposure chamber

The measurement of the size distribution of surgical smoke particles in the breathing zone was conducted under different air exchange rates, air exchanges per hour (AEH), in the exposure chamber, including AEH = 0 h⁻¹ (calm air), 5 h⁻¹, and 15 h⁻¹. The first was chosen to represent the worst-case exposure scenario; the last is at the lower end of the AEH range used in ORs (Climate by Design International 2016; Facility Guidelines Institute 2014); additionally, one was established between the two values (AEH = 5 h⁻¹).

Aerosol measurement for assessing the respiratory protection against surgical smoke

In the tests involving respirator-wearing subjects, two synchronized and simultaneously operated P-Trak condensation particle counters (Model 8525, TSI Inc., Shoreview, MN, USA) were used to measure the total aerosol concentrations outside (C_{out}) and inside (C_{in}) of the tested respirator in a particle size range of approximately 20 to 1,000 nm. Each test was performed over a 10-min period with the P-Trak data recorded every 6 s (resulting in 100 data points). The simulated workplace protection factor (SWPF) at each time point t was calculated as $(C_{out})_t / (C_{in})_t$. Based on these data, the GM and GSD of the time-weighted average SWPF were determined for

Table 1. Selected specifications of the four particle size spectrometers used in the study.

Instrument	Measurement principle/module	Sampling flow rate (L/min)	Particle size range measured (nm)*	Number of channels deployed for measurement	Number of channels within the core particle size range of 40–200 nm
NanoID (Model: NPS500, Particle Measuring Systems, Boulder, CO, USA)	Planar differential mobility analyzer	0.2	17–500	16	7
ELPI (Dekati, Kangasala Ltd., Finland)	Low-pressure cascade impactor with the particle electrical charge detection on impactor plates	30	42–1,000	8	4
SMPS (Model: 3080, TSI Inc., Shoreview, MN, USA)	Differential mobility analyzer and condensation particle counter	10	10–640	7	3
Grimm NanoCheck-Carrier (Model: 1365, Grimm Technologies, Inc., Ainring, Germany)	Faraday cup electrometer (lower size range) + optical particle counter (upper size range)	1.2	13–615	18	6

*The particle size ranges used for the purpose of this study may differ from the overall operational ranges of the instruments.

each tested subject and each tested respirator. The air exchange rate in the exposure chamber was set at $AEH = 15 \text{ h}^{-1}$ for the respiratory protection phase of the study. The air in the chamber was cleaned between the tests by operating the closed-loop HEPA filtration system for 20 min.

Tested respirators

Two models of N95 NIOSH-certified Particulate FFRs (Model 1860 and Model 1870+, 3M Company, St. Paul, MN, USA) were tested on subjects exposed to surgical smoke. These respirators are commonly used by healthcare workers and have been previously evaluated (Casanova and Waka 2013; MacIntyre et al. 2013; Gao et al. 2016; Zhang et al. 2012). Additionally, the above two models were modified by replacing the original faceseal with one incorporating novel design features (Koehler et al. 2014) and then tested under the same conditions as the above commercially available FFRs. Respirators of different sizes were made available for the fit testing of all subjects.

Recruitment of human subjects, training and fit testing

Most of the recruited study subjects were students and staff members of the University of Cincinnati College of Medicine; other health-care professionals were also recruited. Subjects were considered eligible if they were between the ages of 18 and 60 and passed the medical clearance (based on the OSHA questionnaire for respirator users reviewed by an occupational physician). All subjects were trained to perform electrocautery dissection by a board-certified surgeon.

The particle characterization and exposure assessment part of the study was performed via aerosol measurement in the breathing zone of one subject. The respiratory protection part of the study involved a total of 14 subjects. Ten subjects were chosen to evaluate FFR model 1860 (conventional and modified with the faceseal technology). Evaluation of the commercial and modified versions of model 1870+ FFR was intended to be conducted with the same subjects, although four subjects who were no longer available to participate were replaced. The subjects were required to review and sign the consent form approved by the University of Cincinnati Institutional Review Board. The subjects were asked to be clean-shaven and to abstain from eating and smoking for at least one hour before entering the laboratory facility.

Subjects selected for the respiratory protection part of the study were trained on how to wear N95 FFRs to ensure a suitable fit and how to perform a user seal check. Prior to the tests, the subjects were fit-tested using

a PortaCount (Model 8020, TSI, Inc., Shoreview, MN, USA) in accordance with the OSHA protocol that includes the following exercises: (1) normal breathing, (2) deep breathing, (3) turning head side to side, (4) moving head up and down, (5) talking, (6) grimacing, (7) bending over, and (8) normal breathing (NIOSH 1997). A particle generator (Model 8026, TSI Inc., Shoreview, MN, USA) was deployed to provide sufficient aerosol concentration of sodium chloride particles during the fit test (at least $1000 \text{ particles/cm}^3$, typically $10,000 \text{ particles/cm}^3$). The fit factor (FF) for each exercise and the overall FF were recorded. All subjects were required to pass with an overall FF of at least 100 in order to participate in the simulated surgical procedure.

Data analysis

The data analysis was performed using SPSS v.22.0 (IBM Corp., Armonk, NY). A two-way ANOVA followed by pairwise comparisons using Tukey's test was conducted to study the effects of spectrometer and air exchange rate on the size distributions of smoke aerosol. Based on the preliminary findings (Grinshpun et al. 2016) as well as measurement data generated in this study, we examined these effects within the particle size range of 40 to 200 nm (designated as the core range that made a major contribution to the total particle number). In the respiratory protection phase of this study, a paired t-test was performed to investigate the difference in SWPF between the commercial and the modified N95 FFRs. For all the comparisons examined in this study, a p-value of <0.05 represented a significant difference.

Results and discussion

Particle size distribution of surgical smoke in the breathing zone

Figure 2 represents the particle size distributions of surgical smoke measured in the breathing zone with four aerosol spectrometers operating side-by-side. Each point represents GM value of three replicates with the bars representing GSD. The plots are presented for three air exchange rates in the chamber.

All of the particle size distribution curves have a similar shape with the peak being approximately between 60 and 150 nm. Substantial differences between the curves are visually observed in the left tails (small particles of about 10–40 nm) and right tails (particles of 200 nm and above). These differences can be attributed to the differences in measurement principles of aerosols instruments and losses in the sampling lines of the instruments. Even the measurement devices utilizing the same principle

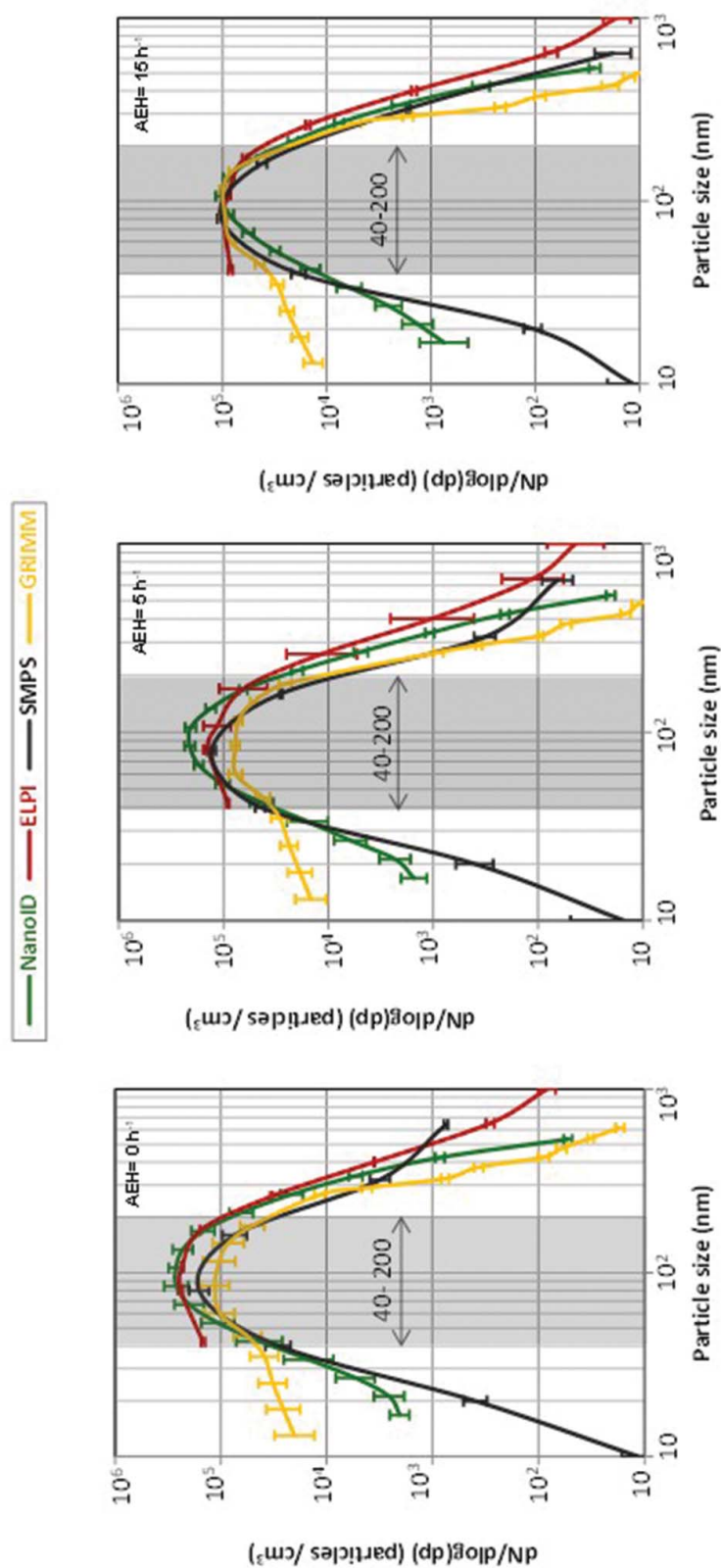


Figure 2. Particle size distributions from electrocautery measured in the breathing zone using four-aerosol spectrometers at different air exchange rates (AEH = 0, 5 and 15 h⁻¹). The shaded area represents the core particle size range. Each point represents the geometric mean value of three replicates and the bars represent the geometric standard deviation.

may produce appreciably different particle size distributions, which is evident, e.g., from the data collected with four collocated SMPSs at the Fresno Supersite (Watson et al. 2011). Particularly large discrepancies (up to 262%) were reported in the quoted study for very small (5–10 nm) and large (200–300 nm) particles. This finding is consistent with our results. Differences among SMPS instruments may be attributed to differences in particle charging efficiency, counting efficiency of a condensation particle counter, particle sampling and transport losses, as well as inaccuracies in the transfer functions of Differential Mobility Analyzers. The above factors are dependent on the particle size. Adding non-scanning instruments, such as ELPI, to the mix may generate additional discrepancies, thus explaining the data observed in Figure 2.

To quantitatively compare results generated by the four spectrometers, a common operational particle size range needed to be established. For instance, the ELPI's lower measurement threshold is approximately 42 nm while the other three instruments start measuring at sizes between 10 and 17 nm. The upper thresholds are also instrument-specific. Additionally, it is seen that the relative contributions of particles below 40 nm and above 200 nm to the total number concentration are rather low. For example, according to the measurements performed with Grimm spectrometer at $AEH = 15 \text{ h}^{-1}$, a total concentration of particles below 40 and above 200 nm was 0.0927×10^6 particles/cm³ while in the range of 40–200 nm it was about 5-fold greater: 0.439×10^6 particles/cm³. The ELPI showed even a much lower relative contribution of the “peripheral” areas as compared to the “core” range (by particle number). Thus, the core particle size range of 40–200 nm was designated for the quantitative analysis.

It was important to compare the aerosol concentration obtained during the simulated surgical procedure to the

background concentration within the same particle size range. Based on the data collected with all the four aerosol spectrometers and three tested air exchange rates, the difference was about or in excess of three orders of magnitude, suggesting a substantial inhalation exposure of unprotected healthcare workers to potentially hazardous particulate matter generated in an OR by electrocautery dissection.

The ANOVA test revealed that in calm air ($AEH = 0 \text{ h}^{-1}$) there were significant differences ($p < 0.01$) in the particle size distributions of surgical smoke measured in the breathing zone by the four aerosol spectrometers. Moreover, pairwise comparison found that there were significant differences ($p < 0.05$) within each pair, except when comparing NanoID versus ELPI, and SMPS versus GRIMM ($p > 0.05$). At $AEH = 0$, the total number concentrations measured in the core particle size range with the NanoID and ELPI were approximately twice greater than those measured with the SMPS and Grimm.

Similarly, significant differences in the particle size distributions measured by the four instruments were found in the tests performed at $AEH = 5 \text{ h}^{-1}$, with a few exceptions in pairwise comparisons: no significant differences ($p > 0.05$) were found between SMPS and GRIMM, and ELPI versus SMPS. However, at $AEH = 15 \text{ h}^{-1}$, no significant differences ($p > 0.05$) were found among the four aerosol spectrometers in measuring surgical smoke. The diminishing difference between data generated by different aerosol spectrometers observed with the increase of the air exchange rate in the room can be attributed to the decrease of the aerosol concentration across the particle size range, which makes the measurement differences less detectable. Although the smoke concentration in the breathing zone – in proximity to the source – may not be affected as much as the overall concentration in an OR, the air purification consistently reduced the particle count as seen from Figure 2.

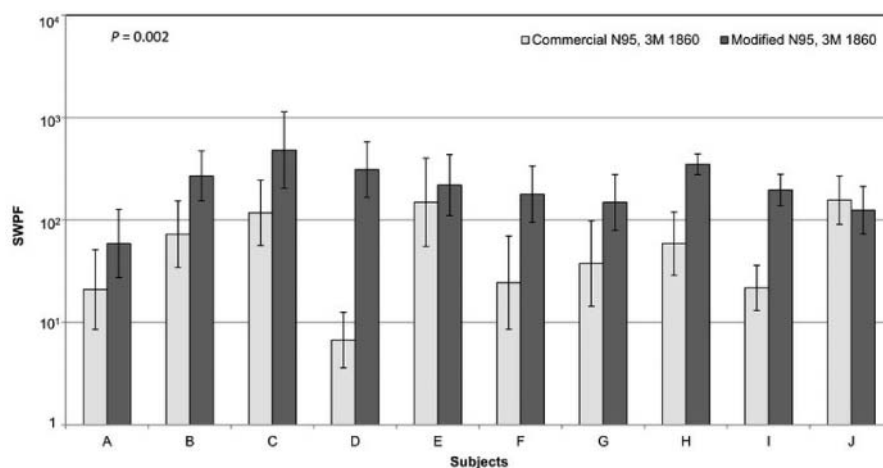


Figure 3A. Simulated Workplace Protection Factor for commercial and modified N95 3M 1860 determined for 10 subjects. Each bar represents GM and each error bar represents the GSD calculated from 100 data points.

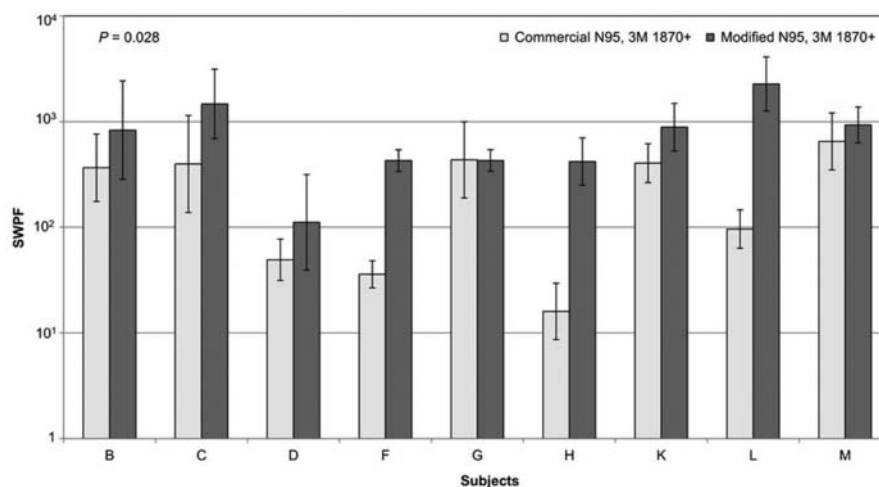


Figure 3B. Simulated Workplace Protection Factor for commercial and modified N95, 3M 1870+ for 9 subjects (the 10th subject was not examined as he/she failed the fit test prior to the chamber experiment). Each bar represents GM and each error bar represents the GSD calculated from 100 data points.

Respiratory protection: SWPF results

Figure 3A represents SWPF values determined for the commercial and modified N95 3M 1860 facepieces for each of the ten subjects. The commercial model had GM = 41 (GSD = 3.5) and the modified model had GM = 197 (GSD = 2.3) with significant difference ($p < 0.002$).

Figure 3B represents SWPF values for commercial and modified N95 3M 1870+ facepieces for 9 subjects (one subject in this test group was excluded as this individual did not pass the fit test with any of the available sizes of the commercial respirator).

The respective SWPF values for the non-modified and modified facepieces were the following: GM = 153 (GSD = 4.2) and GM = 704 (GSD = 2.9), and the difference was again significant ($p < 0.028$). With both respirator models, the modified facepiece resulted in close to 5-fold higher SWPF. This indicates that wearing the modified N95 FFR significantly improves the respiratory protection of subjects against surgical smoke as compared to the commercial N95 FFR. The difference is attributed to the ability of the novel facepiece technology to reduce the respirator facepiece leakage, which has been recognized as the main pathway for particles penetrating into the respirator (Grinshpun et al. 2009; Kim et al. 2015; Koehler et al. 2014; Gao et al. 2016).

Study limitations

The surgical smoke produced in this effort from electrocautery may not be representative for all surgical procedures. First, animal tissue was used in this simulation study; while it is similar to human tissue, some differences in the surgical smoke produced may affect the outcomes. Second, it is possible that different tissues, such

as subcutaneous soft tissue or solid organ tissue, may generate different aerosol concentration levels and particle size distributions than the skeletal muscle tissue used in the present study. The differences may affect the smoke aerosol in ORs, in general, and in the breathing zone, in particular. Some hospital ORs utilize more powerful air purification systems (with greater AEH), which can possibly lower the exposure levels conservatively estimated in the present investigation. The SWPF data were collected for only two models of N95 FFRs, and both were acquired from the same manufacturer; thus, the results may not be fully representative for all N95 models which are commercially available. However, the test conditions established in this study are conservative, and the chosen respirators represent the N95 disposable FFRs rather well; furthermore, these have been specifically cleared by the FDA for use in surgical procedures. A follow-up study may include more surgical procedures, higher air exchange rates, and a greater variety of the N95 FFRs models.

Conclusion

This study was designed to specifically simulate surgical smoke production and exposure in the breathing zone of a surgical provider in a standard operating room environment. The particle size distribution data collected using four aerosol spectrometers revealed similar trends although differences were observed. The peak of the particle size distributions was in a range of 60–150 nm. The concentration of particles generated during the simulated surgical procedure exceeded the background concentration by about three orders of magnitude under the tested air exchange conditions, pointing to a considerable inhalation

exposure to electrocautery-generated aerosol in an OR. Respiratory protection with N95 facepieces is capable of reducing the surgical smoke exposure in an OR. The SWPF data demonstrated that the new face seal technology applied to N95 FFRs significantly enhances the respiratory protection as compared to the commercial N95 facepieces.

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