A Novel Face Seal Design for Filtering Facepiece Respirators: Development and Pilot Testing In a Hospital Operating Room

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ABSTRACT

In this study, we developed a novel face seal (FS) concept for a filtering facepiece respirator (FFR). It is based on the facial anatomic analysis relevant to the respirator contact areas that allow for face seal inward leakage. Prototype respirators were fabricated utilizing the new concept. Two commercially available N100 FFRs were modified by affixing $^1/_4$ and $^3/_8$ inch thick ethylene vinyl acetate (EVA) foam material to the inside periphery of the respirator's shell. Heating of the material was considered as an optional feature. The new respirator was evaluated in a pilot study through a quantitative fit testing, followed by a Simulated Workplace Protection Factor (SWPF) measurement performed in an operating room, where electrocautery smoke was generated by using standard surgical instruments. Both evaluations revealed a significant enhancement, which essentially eliminated the particle penetration through the respirator face seal leakage. The fit factor (FF) increased as much as over two orders of magnitude compared to the conventional N100 FFRs; the SWPF data showed a similar improvement. The effect was primarily attributed to the FS geometry; the heating performed before donning was found to provide a minor additional enhancement, which was not statistically significant. The results of this pilot study suggest that the new design offers considerable advancement in protecting wearers against aerosol hazards, particularly against surgical smoke in operating rooms.

Keywords: Filtering facepiece respirator, face seal, fit, Simulated Workplace Protection Factor, surgical smoke.

INTRODUCTION

Filtering facepiece respirators (FFRs) are used in various occupational environments, including health-care institutions and public health settings, to reduce the wearers' exposure to biological and non-biological aerosols (NIOSH, 2003; OSHA, 2013a). In certain scenarios, e.g., in operating rooms, the FFRs play a dual role protecting surgeons, nurses and other personnel from chemical and biological contaminates arising from the surgical field as well as shielding patients and other surrounding persons from pathogens exhaled by health-care workers. In the US, the FFRs are certified by the National Institute for Occupational Safety and Health (NIOSH) for different levels of protection (e.g., N95, N99, N100), depending on the filter collection efficiency. Another device that is widely deployed in health-care environments is a surgical mask (SM), a comparatively loose fitting device, which was not originally designed to protect the wearer from small airborne particles (it aimed at protecting the wearer from large particles produced by blood splashes as well as the surrounding from the particles exhaled by the wearer). SMs are classified under the Code of Federal Regulations (2012) and cleared for use by the Food and Drug Administration (U.S. Department of Health and Human Services, 2004); SMs are not, however, certified by NIOSH. SMs are required in operating rooms by hospitals and public health agencies governing infection control practices in health-care institutions. In contrast, N95-100 FFRs are not required, except in cases involving laser cautery of lesions containing Human Papilloma Virus (HPV) (Ferenczy et al., 1990), when deployment of N95 FFRs is compulsory according to most of hospital operating policies. Studies as far back as 1961 have confirmed the low efficiency of an SM in protecting the wearer against small particles, primarily because passage of inspired air around its periphery (Green and Vesley, 1962; Lipp and Edwards, 2005; Balazy et al., 2006).

Among various aerosol hazards existing in an operating room, surgical smoke plumes are the most apparent, yet insufficiently investigated. The surgical smoke is generated from the destruction of tissues through the use of thermal energy during surgical dissection. These energy sources include the use of either electrocautery, ultrasonic, laser, or Argon beam coagulation. Such techniques are uniform to nearly all surgical procedures. Electrocautery use is by far the most common energy source in surgical dissection. The smoke can easily be inhaled by the surgical personnel exposed to the operative field. It is estimated that 500,000 workers are exposed to laser and electrocautery smoke each year (NIOSH, 1996; OSHA, 2013b). Studies have shown that a range of aerosolized toxins are present in all surgical smoke plumes (Krones et al., 2007); some of those are either known, or suspected, to be carcinogens (Barrett and Garber, 2003). In addition, surgical smoke plumes have been demonstrated to contain biological particles in a wide range of sizes. Besides HPV, DNA and live virions of the Human Immunodeficiency Virus (HIV) have been found in smoke plumes and shown to be capable of infecting cells in culture (Baggish et al., 1991; Champault et al., 1997). In 2007, the Association of periOperative Registered Nurses (AORN) issued a position paper on the hazards of surgical smoke, updated in 2012, which has been stating in part that "The AORN recognizes that exposure to surgical smoke and bio-aerosols poses a hazard to patients and perioperative professionals… including exposure to odorless toxic gases, vapors, dead and live cellular debris (including blood fragments), and viruses" (AORN, 2013). In order for a respiratory protection device to properly protect the user, in addition to the filter element itself, the device must fit the user's face to minimize the particle penetration though the face seal leakage, which may exceed that through the filter (Grinshpun et al., 2009). Traditional SMs (Rogers, 1980; Pippin et al., 1987), and even more efficient N-type FFRs, have a relatively poor level of protection against the above-mentioned particulate aerosol contaminates due to significant face seal leakage (Tuomi, 1985; Lee et al., 2008; Grinshpun et al., 2009).The leakage has been shown to occur in various FFRs (Chen and Willeke, 1992; Oestenstad and Bartolucci, 2010; He et al., 2014), and to an even greater degree in SMs (Rogers, 1980; Pippin et al., 1987; Lipp, 2005; Oberg and Brosseau, 2008); this negatively affects the protection factor (PF) provided by these devices.

The face seal inward leakage is dependent on multiple factors, including the overall design of the FFR and specifically of the face seal component, the material used, and the mechanism of attachment of the FFR to the wearer's face. It also depends on the particle size (Myers et al., 1991; He et al., 2013). The leakage problem may also be compounded by FFRs being made in fairly generic "small, medium, and large" sizes, and often simply as a "one size fits all" design. Most reports, however, agree that the overwhelming factor in the inward leakage is the face seal itself (Oestenstad et al., 1990; Grinshpun et al., 2009; Cho et al,. 2013).

Anthropometric studies on respiratory protection reveal the substantial differences in the multiple variables of human facial anatomy (Zhuang et al., 2005; Zhuang et al., 2010). These differences are notable in the three most common areas where the face seal leakage has been identified: (i) the nasal bridge to the cheek bone; (ii) the cheek bone to the edge of the lower jaw; and (iii) the area between the undersurface of the chin, back toward the angle of the jaw (Oestenstad et al., 1990; Roberge et al., 2011). Many conventional facepieces have been designed to address only the nasal bridge region; none address all three zones.

To tackle the above issue, a new face seal (FS) concept was developed (U.S. Patent and Trademark Office, 2014) based on: (1) specifically defined facial anatomic zones (FAZs) identified in human facial anatomy, corresponding to the three areas (i)-(iii) associated with a poor seal and (2) modification of these areas by introducing a "filler" of a unique configuration, which is made of a thermoplastic copolymer enhancing the respirator fit to the user's face.

In this pilot study, we fabricated respirator prototypes and evaluated them through fit testing as well as in a hospital operating room against surgical smoke. The fit factor (FF) and simulated workplace protection factor (SWPF) were determined while donning the new respirators on subjects.

DESIGN OF THE NEW RESPIRATOR

Figure 1 illustrates the three principle FAZs (I-III) of the human face involved in the face seal. These are anatomically defined as (Strandring et al., 2008):

- " Zone-I" being the area that includes the Rhinion (also known as Osseocartilaginous Junction or "Nasal Bridge") (1), the NasoMaxiliary Ridge/Process (2), the Maxillary Zygomatic Ridge (3), and partially the Zygomatic Process (forward ridge "cheek bone") (4) ;
- "Zone-II" being the area that includes a part of the Zygomatic Process (4), the Bucchal Wall Soft Tissue Structures (5), and the Mandibular Ramus, Body Inferior Rim (6); and
- "Zone-III" being the area between the two bodies of the Inferior Mandibular Rami (6) on either side of the face, also known as the Submental Soft Tissues (7).

The prototype was fabricated by modifying a conventional facepiece in which the original face seal was replaced with the new FS affixed to the inner peripheral area. Figure 2 illustrates the FS affixed to the inside perimeter of a typical cup shaped mask shell. In the FS design, the anatomic zones I-III (shown in Figure 1) have been compensated for by specific reciprocal areas I-III, along the inner perimeter of the FS. The FS-to-FAZ interface is essentially analogous to a jigsaw puzzle piece fitting to its reciprocal piece: i.e., FAZ-I to FS Area I; FAZ-II to FS Area-II; FAZ-III to FS Area-III.

The FS was made of ethylene vinyl acetate (EVA) foam (McMaster-Carr, Robbinsville, NJ, USA) that was attached using a heat-resistant silicon based adhesive (Permatex Sealant #81730; TW Permatex Inc., Solon, OH, USA). Twelve hours were allowed for drying prior to use.

The new FS was applied to two commercially-available N100 respirators. The N100-grade was chosen because its filter has a very high collection efficiency of >99.97% (which translates to penetration of <0.03%) while the fit requirement allows up to 1% penetration (the "pass" threshold of FF= 100 is applied in the fit testing). This suggests that a vast majority of the particles penetrating inside the respirator enters through the face seal leaks, making the case particularly relevant to the focus of this study. Figure 3 illustrates the FS donned on the human face, without the mask shell attached, demonstrating the interface of the FAZs with the inner perimeter design of the FS.

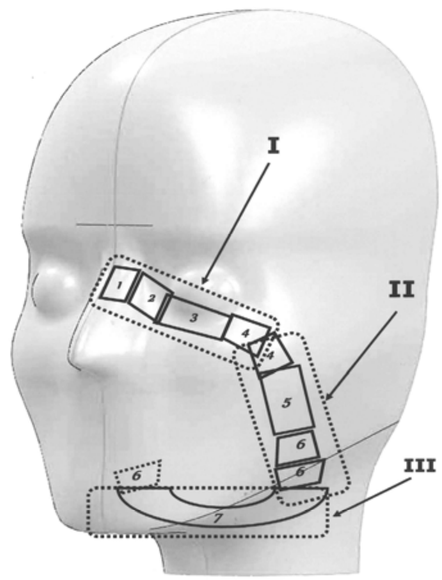

Figure 1. Facial Anatomic Zones I-III, with anatomic structures 1-7 (schematics).

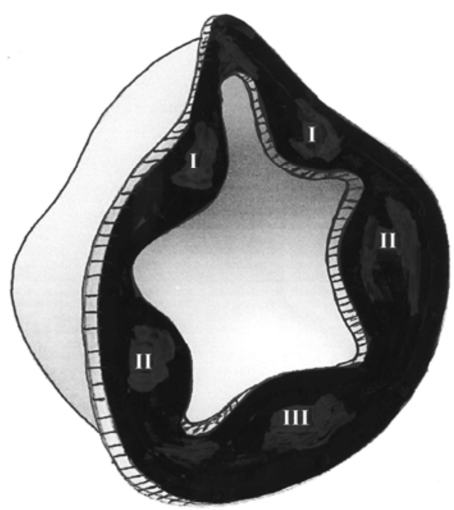

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Figure 2. The new face seal attached to inside perimeter of a cup-shaped respirator shell with areas I-III targeting the Facial Anatomic Zones I-III, respectively.

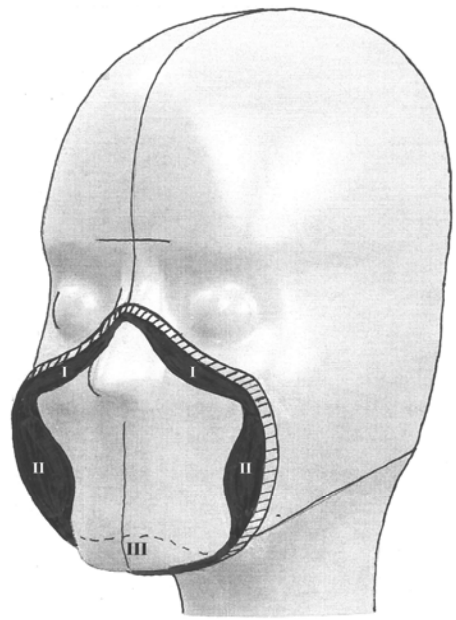

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Figure 3. The new face seal on the human face.

The newly-developed prototype can be used with and without heating the FS material prior to the respirator use. The heat-activation option was exercised in some experiments. A conventional heat gun (Ryobo Mod. HG600, One World Technologies, Inc., Anderson, OH, USA) was deployed at a set temperature of 260°C (500°F). The gun was held at a distance of 2 inches from the FS surface, and the heating was carried out for approximately 2 min using constant motion around the surface. Subsequently, we observed a transition in the appearance of the EVA foam surface – from flat back to glossy black. After heating, the respirator prototype was donned by the user with the holding straps adjusted to obtain a secure fit. A distinct property of the EVA is a low heat accumulation during the thermoplastic molding phase; this helps to avoid any discomfort associated with interaction between the heated material and the human skin during initial donning. After donning the respirator, a "waiting" period of 1.5 min was allowed for the EVA material to cool enough to set in its new, face-adapted shape before the testing began.

EVALUATION OF THE NEW RESPIRATOR (METHODS)

First Prototypes and Fit Testing

A total of four prototypes were made using two N100 FFRs acquired from different manufacturers (further referred as Models A and B), which were modified by affixing $^{1}/_{4}$ and $^{3}/_{8}$ inch thick EVA material to the inside periphery of the respirator's shell (Figure 2). The respirator's exhalation valve was left undisturbed. The EVA material was heated, as described above, before donning.

A subject was fit tested with each of the four prototypes using a PortaCount Plus (Model 8020, TSI Inc., St. Paul, MN, USA) and following the OSHA protocol (OSHA, 2004). Additionally, for comparison, the subject was fit tested with the non-modified respirators A and B (controls). Each test was conducted in three replicates (three donnings). A user seal check was performed prior to each donning. The tests (6x3=18) were conducted in random order.

During fit testing, eight exercises were performed sequentially: 1) normal breathing, 2) deep breathing, 3) moving head side to side, 4) moving head up and down, 5) talking, 6) grimace, 7) bending over, and 8) normal breathing (again). A sodium chloride solution (NaCl, 1%, w/v) was aerosolized in a room-size respirator test chamber (24.3 m^3) by a particle generator (Model: 8026, TSI Inc., St. Paul, MN, USA).

The Fit Factor (FF), a time-weighted average ratio of the aerosol concentration outside and inside the respirator, was recorded for each fit test. A geometric mean (GM) and geometric standard deviation (GSD) were calculated for the three replicates obtained for each test condition.

Comparisons were performed between log-transformed FF-values obtained with modified (prototypes) and non-modified (controls) respirators as well as between those found for the modified respirators with different thicknesses of the added FS EVA material. As a result, the prototype with the highest FF was chosen for further evaluation (referred to as the “new respirator”).

Subsequently, the chosen prototype and its respective N100 control were fit tested in a clinical setting while worn by an experienced board certified general surgeon. No NaCl aerosol was generated in this test. In this phase of the study, the new respirator was tested respectively with and without heating done prior to the donning (to determine the role of heating effect). Again, each fit test was conducted in three replicates (three donnings), and the GM and GSD were calculated for the measured FFs. Comparisons were performed between the FFs obtained with and without heat activation; those were also compared to the control (non-modified respirator).

Determining the Simulated Workplace Protection Factor (SWPF)

The new respirator with and without the pre-donning heat activation was evaluated in a fully functional hospital operating room with temperature and humidity controls as well as standard negative air flow. An electrosurgical generator unit (Valleylab Force FX, Covidien, Boulder, CO, USA) was set at a power of 40 wt. A standard electrosurgical pencil (Valleylab E2516) was intermittently applied to a section of animal tissue following a conventional surgical procedure. The manipulation performed over a period of 2 min generated a visible surgical smoke aerosol. The new respirator (as well as a non-modified respirator) was donned on a human subject performing the simulated procedure. Two P-Trak particle counters (Model: 8525, TSI, Inc., St. Paul, MN, USA) were used to measure the aerosol concentration outside and inside the tested respirator following the experimental protocol utilized in several previous studies (Balazy et al., 2006, Cho et al., 2013, Grinshpun et al., 2008, Lee et al., 2008, He et al., 2013). The P-Trak is capable of real-time measuring the total concentration of particles of >20 nm (with no size discrimination). A 1/10 dilution was applied when the ambient concentration was expected to be greater than 500,000 cm^{-3}, which is the P-Trak’s upper threshold. The aerosol measurement was conducted continuously for the above-mentioned 2-min period. The SWPF was determined as a ratio of the outside and inside time-weighted average aerosol concentrations.

Three human subjects with vastly different anthropometric characteristics were recruited for the SWPF measurements, including the surgeon who was fit tested in the previous phase of the study (see the section above). Each subject positioned himself/herself at a 30 cm distance from the surgical site. Each SWPF test was conducted in three replicates (three donnings), and the GM and GSD values of a subject’s SWPF were calculated. The GM and GSD were also calculated for the three subjects. Thus, within-subject and between-subject data variability was quantified. Comparisons were performed between the SWPFs obtained with the new respirator (with and without heat activation) and the non-modified one.

Statistical Analysis

Data analysis was performed using the SAS version 9.1 (SAS Institute Inc., Cary, NC, USA). The GM and GSD values were determined for each test conditions. FF and SWPF data were log-transformed prior to the data analysis to acquire normality. A one-way analysis of variance (ANOVA) test was performed using the PROC GLM (General Linear Model) to study the effect of the respirator model (control, unheated, and heated) on FF and SWPF, followed by multiple pair-wise comparison tests using the Duncan's Multiple Range Test. Results were considered statistically significant for *p*-values < 0.05.

RESULTS AND DISCUSSION

Fit Factor

Figure 4 presents the FF data obtained with four prototypes and two control respirators. Both modifications of the Model A respirator (with $^1/_4$- and $^3/_8$-inch thickness of the added EVA peripheral material) showed significantly better fit than the control (FF = 685 and 4,163, respectively versus 34, $p<0.05$). The $^3/_8$-inch version produced about 6-fold higher FF-values than the $^1/_4$-inch one ($p<0.05$). Similar results were obtained for Model B, which showed higher FF-values for all three respirators as compared to Model A. Overall, the fit testing revealed data variability with GSD ranging from 1.1 to 3.1.

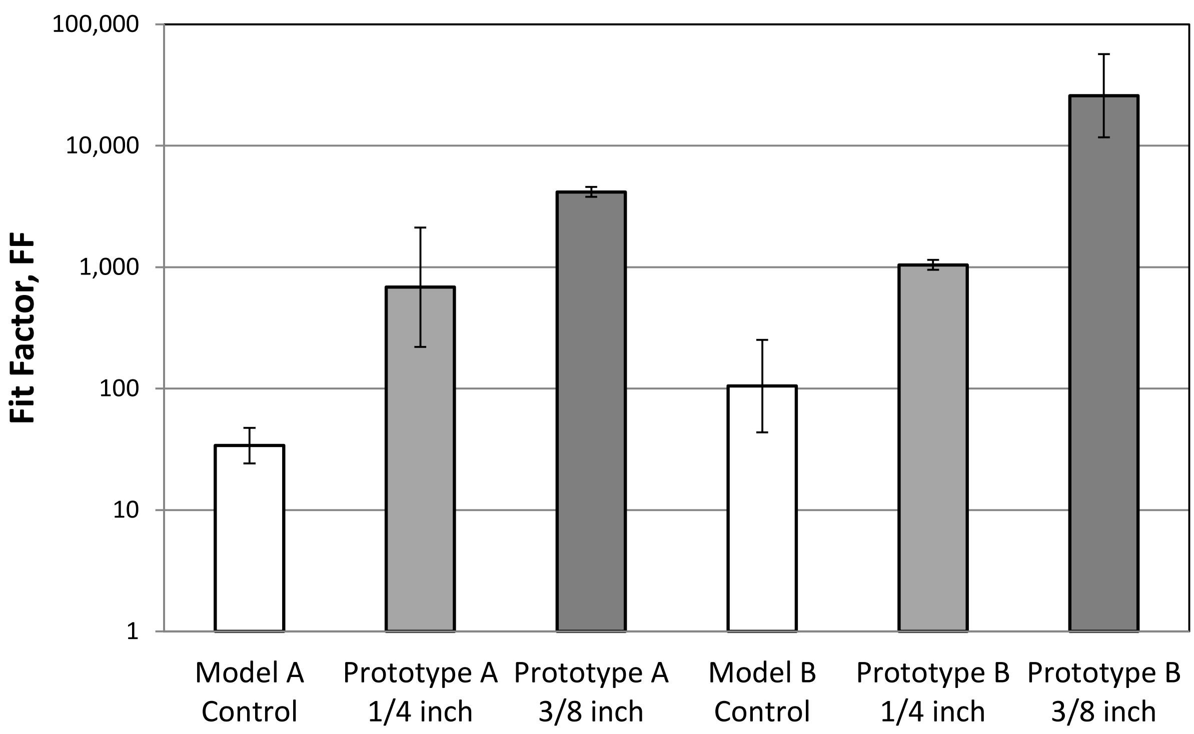

Figure 4. Fit Factor averaged over three donnings (one subject) for two control and four prototype respirators (with heating).

It was concluded that the new FS, when affixed to both N100 FFRs, significantly ($p<0.05$) improved their fit. Remarkably, the subject who did not pass the fit test with the Model A control respirator (FF<100) and barely passed it with the Model B control, achieved FF-values as high as about 10^3–10^4 due to the peripheral modification. The FF-value of 25,808 (GM for the Model B $^3/_8$-inch version) corresponds to the particle penetration of 0.0039%, which is considerably below the penetration expected from solely an N100 filter, not even considering the face seal leakage (the filter collection efficiency is supposed to be 99.97% or above, which translates to the filter penetration <0.03%; thus, FF>3,300 can be interpreted as a fit allowing virtually no room for a measurable face seal leakage in the N100 FFR.

The prototype utilizing Model B and a thicker material ($^3/_8$-inch) showed the best performance ($p<0.001$). Therefore, this prototype was chosen for further studies.

The fit testing of the new respirator on a surgeon in an operating room confirmed that it significantly outperforms the control N100 FFR (with FFs approaching 10,000 for the former while barely passing the 100 benchmark for the latter). The FF-values were found statistically the same regardless whether or not the peripheral area was heated before donning ($p>0.05$). We are not certain if the above finding should be taken as evidence that heating does not improve the fit of the new respirator because the aerosol concentration measured inside the respirator was sometimes as low as several particles per cm^3 (obviously, due to its great fit), which creates a challenge in differentiating the two cases.

Simulated Workplace Protection Factor

Table I presents the SWPF data (range, GM and GSD) obtained with the three tested subjects wearing the new respirator with and without heat activation while being exposed to surgical smoke in the operating room.

Table I. SWPF Data for the New Respirator

Subject #	Simulated Workplace Protection Factor (three donnings per subject)					
	Range		GM		GSD	
	with heating	without heating	with heating	without heating	with heating	without heating
1	7,573 – 56,154	6,494 – 33,810	27,556	12,842	2.4	1.9
2	4,584 – 9,935	6,970 – 67,185	7,028	22,917	1.3	2.2
3	41,196 – 112,502	8,947 – 64,111	79,947	32,659	1.6	2.4

The SWPF values obtained for the Model B control facepiece were much lower: 11.5 – 626 for Subject 1 (GM = 164.5, GSD = 5.9), 27.4 –1,442 for Subject 2 (GM = 240.3, GSD = 4.3), and 35.6 – 137 for Subject 3 (GM = 77.9, GSD = 1.7).

The SWPF values averaged over the entire data base (three subjects, three donnings on each) are presented in Figure 5 for each FFR. Both the heated and non-heated versions produced high level of protection with SWPF exceeding 20,000; both were found to significantly ($p<0.01$) overperform the control, which produced SWPF of 146 (GM). The heat activation resulted in about 15% increase in the SWPF; however, this increase is not significant ($p>0.05$). Considering the fit testing data and the SWPF measurements, no evidence was found that heating of the FS EVA material plays a critical role in improving the respirator performance. While for all three FFRs, both the within-subject and between-subject data variability is substantial, Figure 5 demonstrates that the overall variation was lower for the new respirator (with and without heating) compared to the control.

Study Limitations

There are several limitations in this pilot study, mostly associated with the number of subjects tested and a single surgical procedure used to generate the smoke (besides electrocautery, the surgical smoke generated by sources such as ultrasonic, laser, and Argon beam coagulation can be considered in future efforts). It is also acknowledged that the smoke-generated surgical procedure was exercised on an animal tissue; additional studies involving a human subject being operated will enable the investigators to determine an actual (not a simulated) workplace protection factor. Finally, it should be emphasized that the pilot evaluation of the new FS concept was conducted using the first generation of the laboratory-made prototypes. The design of the prototypes could be further improved, e.g., through applying a 3D digital mapping of FAZs determined for individual subjects featuring different facial anatomic characteristics.

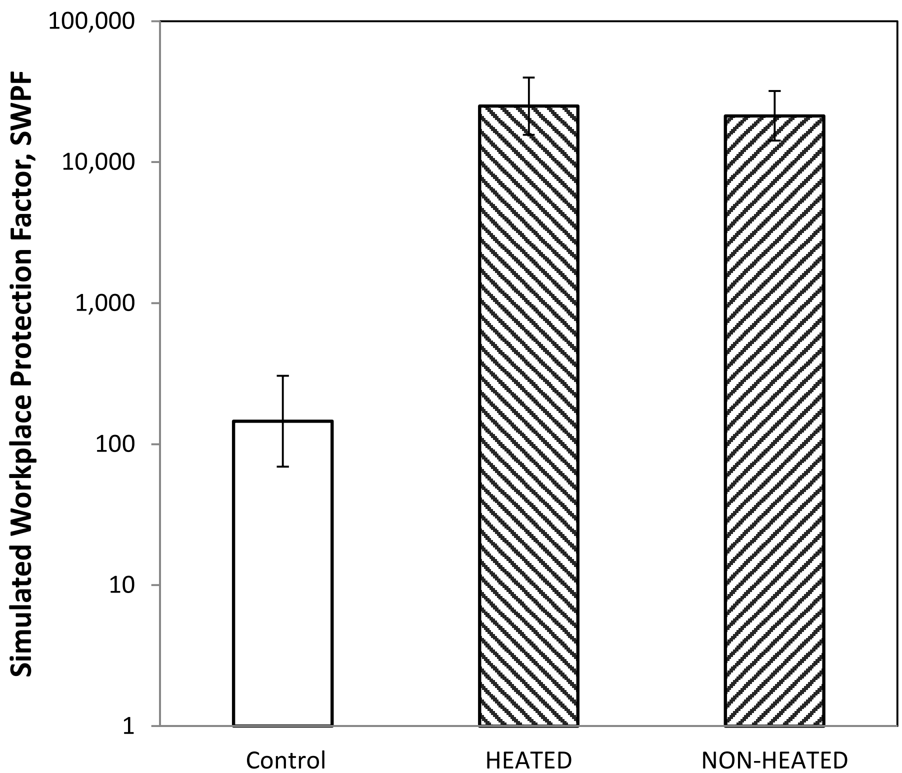

Figure 5. Simulated Workplace Protection Factor averaged over nine tests (three donnings on each of the three subjects) for the control and new respirator with and without heating. Evaluation in the operating room during electrocautery-based surgical procedure.

CONCLUSIONS

The novel FS design was applied to N100 FFRs and the prototypes were performance-evaluated through a quantitative fit testing, followed by a SWPF study in an operating room setting, where a surgical smoke aerosol was generated using electrocautery mimicking a standard surgical procedure on an animal tissue. Both evaluations revealed a significant enhancement, which essentially eliminated the particle penetration through face seal leakage. The FF increased as much as over two orders of magnitude compared to the conventional N100 FFRs: the SWPF showed a similar improvement in protection against surgical smoke. The improvement can be primarily attributed to the design of the FS affixed along the periphery to target the FAZs, where the face seal leakage is expected to be most substantial. The heating of this material before donning may further enhance the respirator performance; its effect is likely dependent on the wearer's anthropometrics and other factors. However, no evidence was found in this investigation to demonstrate that the heating produced significant additional improvement. The results of this pilot study suggest that the new design has a great potential in offering a much advanced protection against aerosol hazards, including surgical smoke in healthcare settings.

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