HHS Public Access

Author manuscript

Am J Infect Control. Author manuscript; available in PMC 2024 March 01.

Published in final edited form as:

Am J Infect Control. 2020 February ; 48(2): 153–156. doi:10.1016/j.ajic.2019.08.009.

Sterile field contamination from powered air-purifying respirators (PAPRs) versus contamination from surgical masks

Rex A. Howard, DVM[*],

George W. Lathrop, DVM, DACLAM,

Nathaniel Powell, DVM, MS, DACLAM

Comparative Medicine Branch, Division of Scientific Resources, Centers for Disease Control and Prevention, Atlanta, GA

Abstract

Background: Currently, powered air-purifying respirators (PAPRs) are not recommended for usage in close proximity to sterile fields owing to concerns that exhaled, unfiltered air potentially may cause contamination; however, this has not been confirmed by experimental study.

Methods: After establishing background levels of airborne contamination, our team placed settling plates in a sterile field and collected contamination from participants who were performing particulate-generating actions. Participants performed the actions while wearing various forms of respiratory protection, including: (1) a full facepiece PAPR, (2) a full facepiece PAPR with a shoulder-length hood, (3) a surgical mask, and (4) no facial covering (as a positive control to determine contamination-reduction effectiveness). Specimens were collected at the end of a 10-minute sampling time frame. After incubation at 36.58C for 72 hours, we tabulated colony forming units as a marker of contamination.

Results: Surgical masks and the 2 PAPR configurations all drastically reduced aerosolized droplet contamination. Surgical masks reduced contamination by 98.48%, and both PAPRs reduced contamination by 100% (compared with the usage of no facial covering). There was no statistical difference between their effectiveness (surgical mask vs both PAPRs, *P* value = .588 and no hood PAPR vs hood PAPR, *P* value >.999).

Discussion/Conclusions: Based on these findings, the tested PAPR configurations are effective at reducing aerosolized droplet contamination into a sterile field, and further testing is warranted to assess other PAPR configurations as well as PAPR suitability in an operating room.

Keywords

Surgery; Aerosol; PPE; Nosocomial

Surgical masks are used in the medical field to protect patients from aerosolized droplets emanating from the mouth or from the nose of the user; however, they do not provide

[*]Address correspondence to Rex A. Howard, DVM, Comparative Medicine Branch, Division of Scientific Resources, Centers for Disease Control and Prevention, CDC MS H23-2, 1600 Clifton Rd, Atlanta, GA 30329., MSN2@cdc.gov (R.A. Howard).

Conflicts of interest: None to report.

significant respiratory or comprehensive splash protection. Medical and veterinary medical personnel who treat patients with infectious diseases require increased levels of respiratory and splash protection, in addition to the necessity of providing sterile procedures for patient protection. Powered air-purifying respirators (PAPRs) are a technological advancement that have improved the respiratory protection of workers in numerous fields and may be an option to fill this niche. PAPRs have several noted advantages over other configurations of respiratory and splash protection used within the medical and research fields. They have chemical vapor protection, if the appropriate cartridge is used, and the high-efficiency particulate air (HEPA) filters used with many models provide excellent particulate filtration for respiratory protection.[1] The Occupational Safety and Health Administration respiratory assigned protection factors (APFs) for half-mask, full facepiece, and loose-fitting facepiece PAPR configurations are all higher than those for the APF for a conventional half-mask respirator air-purifying respirator.[1,2] The constant airflow provided by the PAPR may reduce the environmental heat stress frequently encountered with extended use of personal protective equipment (PPE).[3] Because of the need to protect against airborne particles, PAPR face shields are an integral part of the respirator and provide an uninterrupted barrier for splash protection to the face, whereas face shields that are not part of respirators often have open quadrants on the lower portions. These open areas allow splashed, coughed, or sprayed fluids/particles a potential angle of entry to the mucous membranes and orifices of the user.[4] Not all forms of safety goggles/glasses can mitigate this splash risk because they are incompatible with filtering facepiece respirators, owing to physical impedance.[4]

Although studies indicate that PAPRs effectively protect the user from airborne particulates and splashes, they do not address the extent that PAPRs may inhibit user-generated contamination from affecting a sterile field or a surface in an operating room (OR). Current guidance from the National Personal Protective Technology Laboratory and the Association of periOperative Registered Nurses (AORN) does not recommend the usage of a PAPR in an OR owing to a lack of scientific evidence to support safe usage and the possible contamination of the wearer's exhaled, unfiltered air onto the sterile field.[5] This guidance is founded on a reasonable supposition; however, it may be unnecessarily limiting the PPE options available during medical procedures in which there is a risk of exposure to staff. The purpose of this study was to evaluate this guidance to determine if the presumed risk to the patient or sterile field is increased by PAPR usage. The hypothesis for this experiment is that PAPR usage in a surgical environment is as effective as the usage of a surgical mask in reducing aerosolized droplet contamination into a sterile field. Our research team elected to use surgical masks for comparison against PAPRs because surgical masks are accepted as the standard respiratory PPE for protection of the patient and sterile field.[6]

METHODS

Prior to each iteration of testing, a researcher placed an Anderson impactor (Tisch Environmental, Inc, Village of Cleves, OH) in a designated OR to establish the background airborne contamination level.[7] The OR was part of a surgical suite regularly used to perform veterinary surgeries. The impactor had 6 stages, ranging from 0.65 μm up to 1.18 mm. The Anderson impactor used specialized glass petri dishes loaded with 27 mL of a nonselective agar (tryptic soy agar plus sheep blood agar). The Anderson impactor operated at a rate of

28.3 ± 0.1 L/min for 20 minutes each time (for a total of 566 ± 2 L for each iteration). The impactor was placed on the surgical table 1 m above the ground and at least 1 m from all walls and doors. The OR was supplied with HEPA filtrated air with net positive pressure (when compared with connecting corridors) that was refreshed at a rate of 11.6 total air exchanges per hour. We measured and recorded the temperature and relative humidity prior to the start of each iteration as well.

To test the effectiveness of various respirators and masks to inhibit contamination of a sterile field, masked participants performed a standard battery of movements and breathing patterns while in close proximity to a sterile field. Contamination was then quantified by counting colony-forming units (CFU) on settling plates placed into the sterile field. Settling plates were used instead of Anderson impactors to sample the sterile field since aerosolized droplets typically settle within 1 m of the point of generation (owing to their size) and smaller, airborne particles would be less likely to settle into the sterile field.[8] The sterile field was established on the OR stainless steel surgical table. A standardized table height of 55 cm was established from the chin of each participant to the table top, based on average typical surgical distances preferred by the 4 participants. The participants also stood in a position that maintained their torsos 10 cm from the table edge. We established this distance of separation from the table to minimize variables between participants, such as either movement/shifting against the table, generating minute air currents or participants excessively leaning over the table. Four plastic agar plates, with a diameter of 10 cm and loaded with a nonselective agar of tryptic soy agar plus sheep's blood, were placed as settling plates around the central portion of the sterile field. These settling plates were used as a representative surface area for the sterile field as a whole.[7] The plates were placed with their centers 18 cm from each other in a square pattern, with the 2 closest to the participant placed 18 cm from the table edge, as measured from the center of the petri dish. These distances were chosen to maximize sampling surface area within the confines of the surgical table, to establish settling plates on both the left and right of each participant, and to sample the near and far sides of the sterile field. The total surface area of the 4 combined agar plates was 314.16 cm^2.

The 4 participants selected to test the masks were familiar with aseptic techniques and used PPE in accordance with AORN guidelines for surgical attire, with the exception of varying facial coverings. This PPE included an impervious surgical gown, sterile gloves, disposable foot covers, disposable hair covers, and the variable respirators/masks.[6]

Each participant conducted the testing with 10 minutes of sampling for each variation of facial covering and in the following order: surgical mask, loose-fitting facepiece PAPR with a hood to the shoulders, loose-fitting facepiece PAPR with no hood, and no facial covering. All 4 agar plates were changed between each variation. The interval between sampling was untimed and was dependent on the time required to change agar plates and facial coverings (estimated as typically 3–4 minutes). Only 1 battery of testing (with 1 participant) was performed each day.

The surgical masks (S-10478; Uline, Pleasant Prairie, WI) were generic and in compliance with AORN guidance that the mask should fully cover both the mouth and the nose and

be secured in a manner that prevents venting.[6] The masks also had a semiflexible strip for folding over the nose and elastic bands that wrapped over the ear pinnae to secure it in place.

S-533 Hood (Hood PAPR Group)

The PAPRs (Versaflo 600, 3M, St Paul, MN) used HEPA filtration and were set to run at a flow rate of 185 L per minute. [9] The hooded facepiece (hood PAPR group) had a water-resistant drape that extended to the shoulders of the wearer (Versaflo Hood S-533; 3M).[10] The internal edges of the face piece and the hood were kept adjacent to the skin of the wearer with an elastic margin. When the sterile gowns were placed on the participant, the gown was placed with the drape of the hood under the neck margins of the gown. Air exhaust from the S-533 vented either underneath the drape and gown or through a permeable fabric filter located in front of and below the chin of the wearer.

The other PAPR mask (no hood PAPR group) consisted of a full face shield, dorsal head covering, and a water-resistant fabric that extended underneath the jaw of the wearer and caudal to a point just rostral of the ears (Versaflo Headcover S-133; 3M).[11] The edge of the fabric was held against the skin of the wearer by an elastic margin, and this mask lacked any form of drape, beyond the fabric extending from the face shield to the face of the wearer and the portion over the top of the head. Like the S-533 hood, the S-133 also had a permeable

fabric filter located in front of and below the chin of the wearer to facilitate air exhaust. Neither the S-533 nor the S-133 had any form of exhalation valve that would allow direct, unfiltered venting onto the sterile field.

S-133 Headcover (No Hood PAPR Group)

The use of no facial covering (no mask group) was to provide a common basis of contamination reduction and to serve as a positive control.

During each 10-minute testing interval, the participant assumed 3 predetermined head positions. At each position, participants did the following: recited the “Rainbow Passage,” coughed twice, performed 1 deep exhalation through the nose, and performed 1 deep exhalation through the mouth.[12] One head position was angled at 45° to the left of the center and 1 head position was angled at 45° degrees to the right from the center, with 2 minutes at each position. The same tasks were performed with the head centered and focused on the sterile field during the remaining 6 minutes. The purpose of changing head positions was to simulate various head motions, which may lead to air leakage at the edges of the masks. The exhalations, talking, and coughs were used to simulate common circumstances that may cause environmental contamination of the sterile field. Prior to execution of the tasks, each participant was trained to simulate an approximate standardized forcefulness and volume for the speaking, coughing, and exhalations.

Agar plates were collected and stored in a controlled-temperature incubator for 72 hours at 36.58°C ± 1°C, with counts of colony-forming units (CFU) measured at the 24, 48, and 72 hour time points. To eliminate potential bias, the same researcher performed the CFU

counts of all plates and was blinded to which plates were used with the various respirators. The CFU counting was performed in a class II biosafety cabinet to prevent posttesting contamination.

At the conclusion of CFU counting at 72 hours, representative colonies from the sterile field trial plates and the Anderson impactor plates were collected. The isolated colonies were then analyzed with mass spectrometry (version biotyper 2.0; Bruker Daltonics, Billerica, MA) to identify the organisms. The colonies were first inactivated using the formic acid extraction method described in the unit's user manual.[13] The software compared spectrometry signatures from isolated colonies to a database of established bacterial spectra. The software then compared the level of similarity and provided a list of organisms that are the closest fit with the analyzed organism, along with a level of confidence for both genus and species. This information was collected to form a generalization of the species that were typically background airborne contaminants versus those that predominantly came from aerosol contamination. The bacterial species data was only included if it had a logarithmic score of 1.700 or higher, meaning at least a probable genus identification. Additionally, if multiple species scored over the 1.700 level for a given sample, the species with the highest score value was listed owing to the higher level of confidence of genus and species identification.

Statistical analysis was performed and Figure 1 was created using Prism 8.0 software (GraphPad, San Diego, CA), whereas basic calculations were performed in a Microsoft Excel spreadsheet program (version 2016; Microsoft Corp, Redmond, WA). A Centers for Disease Control and Prevention Human Subjects Advisor determined that Institutional Review Board review of these experiments as unnecessary.

RESULTS

The background airborne contamination in the OR was measured 4 times (once each week just prior to the sterile field trials) with the Anderson impactor prior to each of the sterile field trials and returned total CFU counts of 2, 2, 2, and 4, averaging 2.500 ± 0.866 CFU/run, or $4.42 \times 10^{-3} \pm 1.53 \times 10^{-3}$ CFU/L of air. Based on the stages where the CFUs were found, the sizes of the initial particles were (in ranges of micrometers) 1.1–2.1 (3 CFU), 2.1–3.3 (2 CFU), 3.3–4.7 (2 CFU), and >7.0 (3 CFUs). This level of background airborne contamination is extremely low, when compared with the Occupational Safety and Health Administration standards for indoor air contamination.[14] The average temperature was 23.1°C ± 0.481°C, and the average humidity was 45.75% ± 1.479% for both the Anderson impactor and sterile field trials. The species recovered for background airborne contamination were: *Micrococcus luteus* (5 identifications), *Staphylococcus epidermidis* (1 identification), *Staphylococcus hominis* (1 identification), and a species that could not reliably be identified (3).

From the combined sterile field trials, the use of no masks resulted in 66 CFU, usage of surgical masks resulted in 1 CFU (*Micrococcus luteus*), and both PAPR configurations resulted in zero CFU. The average CFU per participant (with SDs) were 16.5 ± 10.5 CFU

for the no mask group, 0.25 ± 0.43 CFU for the surgical mask group, and 0 CFU for the PAPR groups.

The contamination density on the sterile field was 0.052/cm^2 for the No Mask group, 7.96 × 10^{-4}CFU/cm^2 for the Surgical Mask group, and 0 CFU/cm^2 for both PAPR configurations.

Figure 1 shows the percent reduction in CFU compared with the no mask group was 98.5% for the surgical mask group and 100% for both PAPR groups.

The statistical significance of each result was compared using a 2-way ANOVA followed by the Kruskal-Wallis multiple comparison test. The surgical mask, hood PAPR, and no hood PAPR each had statistical significance in reduction of CFU when compared with the no mask group (the uncorrected Dunn's test individual *P* values of .0115, .0021, and .0021, respectively). When the surgical mask, hood PAPR, and no hood PAPR groups were compared with each other using the uncorrected Dunn's test, none of them showed a statistically significant difference in reduction of CFU (surgical mask vs both PAPRs had a P value = .588 and the hood PAPR vs no hood PAPR had a *P* value > .999).

The bacterial species found from the sterile field trials were (with the number of identifications in parentheses): *Streptococcus oralis* (4), *Streptococcus infantis* (1), *Streptococcus pneumoniae* (1), *Rothia dentocariosa* (1), *Streptococcus sanguinis* (1), *Micrococcus luteus* (1), *Actinomyces oris* (1), *Staphylococcus epidermidis* (1), *Staphylococcus hominis* (2), and a species that could not reliably be identified (3). The *Streptococcus* spp, Rothia *dentocariosa*, and *Actinomyces oris* are all affiliated with the oral and upper respiratory tract microbiomes, and their presence is suggestive that the source of contamination was predominantly from the participants.

DISCUSSION

Possible sources of error for the Anderson impactor include manually removing/replacing the protective cap on the impactor itself, as well as manually turning the pump on and off. These tasks required a human presence in the room during the initial and last stages of each iteration. The air currents created by the movement and the epidermal cells/dust shed by this human intrusion (despite the usage of gloves and laboratory coats) may have artificially increased the background airborne contamination levels, even though they remained remarkably low.

Sources of error for the sterile field trials include differences in the surgery-mimicking performances by the participants and naso-oral microbiome variations. There is a low possibility of true airborne contamination from particulates in the OR; however, both the very low measured concentration of airborne CFU and the difference in speciation (saprotrophic and epidermal species present for the OR background contamination level vs naso-oral species predominantly present for the sterile field trails) indicate that the primary source of contamination into the sterile field was from the effects of respiration, talking, and coughing of the participants. As much standardization as possible was used while training the participants to perform the various actions, including specific points of reference for the direction to face and practicing coughing to approach a similar forcefulness; however,

numerous variations still likely occurred. The possible variations include (but are not limited to) the facial shape and conformation affecting fit of the masks, the degree of openness of the mouth while coughing or talking, and the presence/absence of facial hair. The density of microbes shed in the aerosols from the participants also likely varied, depending on factors such as composition of previous meals and time elapsed since previous dental hygienics.

The results from this study support the use of surgical masks, hooded, and nonhooded PAPR configurations as effective PPE to reduce user-generated aerosol contamination into a sterile field. Future studies should also incorporate surgical N95 masks for testing and comparison.

There are numerous PAPR hood configurations, and this study cannot be applied to those that do not have an elastic edge maintaining contact with the skin, nor to those that have either holes in the fabric surrounding the face shield or unfiltered exhaust valves. These openings could allow aerosolized droplets to travel unhindered in a direct line-of-sight onto the sterile field. In this experiment, we did not incorporate survey data regarding the PAPR types used most commonly throughout the medical industry; however, future PAPR studies should incorporate other common PAPR configurations to ensure these experimental results can be applied to more of the health care field. These results also cannot be applied to airborne viruses emanating from the PAPR user either, since viral testing samples were not collected and airborne viruses are not limited to aerosol spread.

CONCLUSIONS

Based on these results, further studies of common medically used PAPR configurations are warranted to validate the results of this experiment, and to capture the full extent of PAPR usefulness and limitations. PAPRs are an effective splash protection for the user (with more coverage than face shields alone, which tend to have an open angle at the base), they provide fresh air flow to cool the user, they have a higher APF, and they do not suffer from eyewear incompatibility. In addition, the results of this study indicate that these specific PAPR configurations are as effective as surgical masks for protection of both the patient and the sterile field.

Acknowledgments

The authors would like to thank Genzer, Sarah; Hughes, Laura; Lindsley, William; Maines, Taronna; Mills, Patrick; Moon, Jonathan; Stuchlik, Olga; Svoboda, Pavel; Taylor, Will for their contributions to this study.

References

1. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2018-176. A guide to air-purifying respirators. Available from: 10.26616/NIOSHPUB2018176. Accessed February 5, 2019.
2. Occupational Safety and Health Administration. Occupational safety and health standards: personal protective equipment: respiratory protection: 1910.134(d)(3) (i)(A). https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&p_table=STANDARDS. Accessed February 5, 2019.

3. Occupational Safety and Health Administration. OSHA technical manual, section III: chapter 4, heat stress. Heat-related illness prevention program. Available from: https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_4.html#acclimatization. Accessed February 5, 2019.

4. The National Institute for Occupational Safety and Health. Eye safety: infection control. Available from: https://www.cdc.gov/niosh/topics/eye/eye-infectious.html. Accessed February 5, 2019.

5. The National Personal Protective Technology Laboratory. Respirator trusted-source information. Section 3: ancillary respirator information. Available from: https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3health-care.html. Accessed April 9, 2019.

6. AORN Recommended Practices Committee. Recommended practices for surgical attire. Available from: 10.1016/S0001-2092(06)60424-9. Accessed April 19, 2019.

7. Lindsley WG, Green BJ, Blachere FM, Martin SB, Law BF, Jensen PA, et al. NIOSH. Sampling and characterization of bioaerosols. In: NIOSH manual of analytical methods (NMAM), 5th ed; 2017.

8. Gralton J, Tovey E, McLaws M, Rawlinson W. The role of particle size in aerosolised pathogen transmission: a review. J Infect 2011;62:1–13. [PubMed: 21094184]

9. Technical specifications 3M Versaflo Powered Air Purifying Respirator TR-600. Available from: https://multimedia.3m.com/mws/media/1000749O/3m-versaflotr-600-technical-specifications.pdf. Accessed October 29, 2018.

10. 3M Versaflo High Durability Hood with Integrated Head Suspension S-533L product informational website. Available from: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Versaflo-High-Durability-Hood-with-Integrated-Head-Suspension-S-533L-Medium-Large-1-EA-Case/?N=5002385+3294753635&preselect=3293786499&rt=rud. Accessed July 16, 2019.

11. 3M™ Versaflo™ Headcover with Integrated Head Suspension, S-133L-5 product informational website. Available from: https://www.3m.com/3M/en_US/company-us/all-3m-products/~/3M-Versaflo-Headcover-with-Integrated-Head-Suspension-S-133L-5-White-Medium-Large-5-EA-Case/?N=5002385+3294753641&preselect=3293786499&rt=rud. Accessed July 16, 2019.

12. Occupational Safety and Health Administration. Occupational safety and health standards: personal protective equipment: respiratory protection: 1910.134 App A. Available from: https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.134AppA. Accessed October 10, 2018.

13. BioTyper User Manual, Version 2.0. Bruker Maltronik GmbH; 2007.

14. Occupational Safety and Health Administration. OSHA technical manual, section III: chapter 2, indoor air quality investigation, sampling instrumentation and methods. Available from: https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_2.html#4. Accessed June 24, 2019.

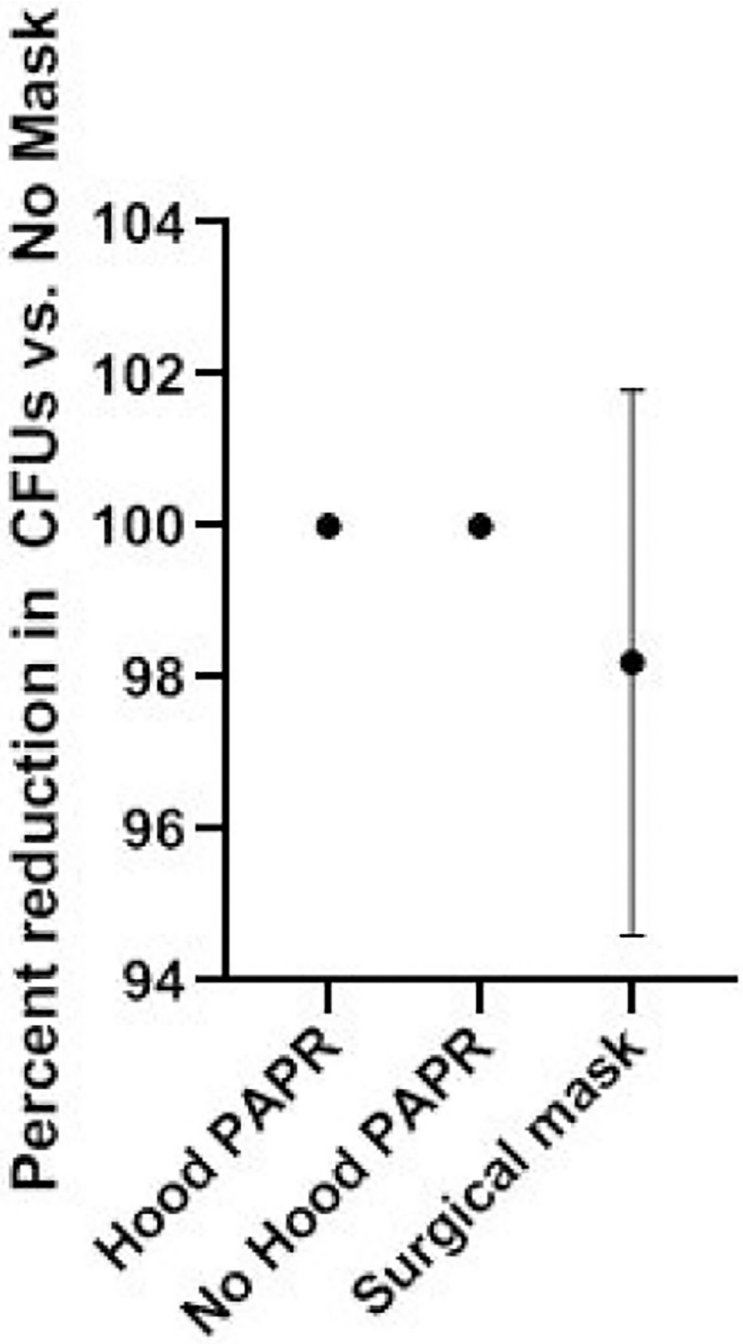

Fig 1.

Both PAPR groups achieved a 100% reduction in CFUs vs no mask, whereas the surgical mask group had 1 CFU present and a 98.5% reduction vs no mask. No statistical difference was found between the PAPR and surgical mask groups' CFU reduction. *CFU*, colony-forming unit; PAPR, powered air-purifying respirators.