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Fit evaluation of NIOSH approved N95 filtering facepiece respirators with various skin protectants: A pilot study

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Abstract

Widespread disease outbreaks can result in prolonged wear times of National Institute for Occupational Safety and Health Approved N95 filtering facepiece respirators by healthcare personnel. Prolonged wear times of these devices can cause the development of various adverse facial skin conditions. Healthcare personnel have been reported to apply “skin protectants” to the face to reduce the pressure and friction of respirators. Because tight-fitting respirators rely on a good face seal to protect the wearer, it is important to understand if the fit is affected when skin protectants are used. This laboratory pilot study included 10 volunteers who performed quantitative fit tests to evaluate respirator fit while wearing skin protectants. Three N95 filtering facepiece respirator models and three skin protectants were evaluated. Three replicate fit tests were performed for each combination of subject, skin protectant (including a control condition of no protectant), and respirator model. Fit Factor (FF) was affected differently by the combination of the protectant type and respirator model. The main effects of the protectant type and respirator model were both significant ($p < 0.001$); additionally, their interaction was significant ($p = 0.02$), indicating FF is affected by the combined effects of the protectant type and respirator model. Compared to the control condition, using a bandage-type or surgical tape skin protectant decreased the odds of passing the fit test. Using a barrier cream skin protectant also decreased the odds of passing the fit test across all models compared to the control condition; however, the probability of passing a fit test was not statistically significantly different from the control condition ($p = 0.174$). These results imply that all three skin protectants reduced mean fit factors for all N95 filtering facepiece respirator models tested. The bandage-type and surgical tape skin protectants both reduced fit factors and passing rates to a greater degree than the barrier cream. Respirator

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Attribution

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users should follow respirator manufacturers' guidance on the use of skin protectants. If a skin protectant is to be worn with a tight-fitting respirator, the fit of the respirator should be evaluated with the skin protectant applied before use in the workplace.

Keywords

Fit test; healthcare personnel; N95 filtering facepiece respirator; NIOSH-approved respirator; skin protectant

Introduction

The COVID-19 pandemic has put frontline healthcare personnel (HCP) at risk of contracting the disease, making it imperative that they wear the appropriate personal protective equipment (PPE) (Hua et al. 2020; Woolley et al. 2020). In healthcare, the most common types of medical-grade respirators used to reduce exposure to airborne transmissible diseases, including COVID-19, are filtering facepiece respirators (FFRs) approved by the National Institute for Occupational Safety and Health (NIOSH) (Goldfrank and Liverman 2008; Woolley et al. 2020). In the United States, the most common class of NIOSH Approved FFRs used by healthcare personnel is the N95 (Wizner et al. 2016).

During the COVID-19 pandemic, it has been reported that HCP wore N95s for extended time periods. According to a survey distributed to HCP in the United Kingdom who were required to wear PPE, respondents answered that the duration of time PPE was used was up to 12 h depending on the shift (Davey et al. 2021). Throughout their shifts, 76.8% of respondents reported they had to doff their PPE for relief, with 32.6% of these respondents doffing their PPE a minimum of five times (Davey et al. 2021). Following prolonged wear times of N95s, HCPs have experienced adverse facial skin conditions (Hornbeck et al. 2020; Hua et al. 2020; Hu et al. 2020; Woolley et al. 2020).

Based on a systematic review and meta-analysis performed in 2020 relevant to the effects of the COVID-19 pandemic on HCP, the estimated overall prevalence of HCP developing an adverse skin condition with extended PPE use was 78%, ranging from 42.8–95.1% among the captured studies (Galanis et al. 2021). From an online questionnaire distributed to nursing staff in 2021 related to occupational PPE use, it was found that 18% of nurses reported having a preexisting skin condition, and 59% stated that wearing PPE for extended periods during the pandemic worsened these conditions (Westermann et al. 2022). HCP who wore N95s for six hours or more were found to be at a higher risk for developing some form of skin condition associated with device-induced pressure or friction, including discomfort, skin dryness and tightness, forms of contact dermatitis, superficial wounds or cuts, and the development of acne or worsening of preexisting acne (Kelechi et al. 2020; Lan et al. 2020; Singh et al. 2020; Bui et al. 2021; Yıldız et al. 2021).

To reduce pressure and friction to the areas of the face that come in contact with FFRs to create a face seal, HCP have been reported to apply barrier creams, medical tapes, adhesive bandages, and hydrocolloidal dressings to their faces (Smart et al. 2020). Tight-fitting respirators, which include N95s, rely on a good seal to the face (verified by passing

a fit test in the workplace) to provide their expected level of protection (OSHA 1998). Additionally, the Occupational Safety and Health Administration's (OSHA) Respiratory Protection Standard does not allow for any interferences between the face and the sealing surface of a respirator (OSHA 1998), thus it is imperative to investigate the degree to which skin protectants affect respirator fit.

Only a few studies have been published in recent years investigating the effects of respirator fit with skin protectant application. Guschel et al. (2020) measured the fit of one N95 model (1860, 3 M, St. Paul, MN) in combination with different types of skin protectants using a PortaCount Respirator Fit Tester (8038, TSI, Shoreview, MN) and its associated OSHA-accepted fit testing protocol (OSHA 1998). Their study only included two test subjects and statistical tests were not performed on the data. N95 fit was evaluated in combination with the application of either a liquid skin protectant (Cavilon Advanced Skin Protectant, 3 M), a transparent film dressing (Tegaderm, 3 M), a light-silicone adhesive dressing (Mepilex Lite, Mölnlycke Health Care, Gothenburg, Sweden), or a hydrocolloidal dressing (DuoDERM Extra Thin, ConvaTec, Bridgewater Township, NJ). For both test subjects, all the skin protectants allowed for passing fit factor (FF) results (>100). The range of FF results was 118–200 across all skin protectant types. The highest FFs (200 for subject 1, and 198 for subject 2) were obtained with the Cavilon protectant (Guschel et al. 2020).

Bui et al. (2021) performed qualitative fit testing on 25 participants who wore one N95 model (1860, 3 M) paired with one of five different protectant types: two types of hydrocolloid dressings (DuoDERM CGF dressing and DuoDERM Extra Thin dressings (ConvaTec, Oklahoma City, OK)), hydrocolloid blister bandages including Band-Aid (Johnson and Johnson) and other generic options, a medical tape (Mepitac Soft Silicone Tape, Mölnlycke, Gothenburg, Sweden), and a barrier film (Cavilon No Sting Barrier Film, product no. 3345, 3 M). The investigators assessed user comfort and respirator fit. The barrier film had the highest passing rate (88%) compared to the other protectants in the study (56–84%) (Bui et al. 2021).

Ng et al. (2022) assessed repeated quantitative fit testing of 134 HCP test subjects who tested four different N95 models in combination with a hydrocolloid dressing (DuoDERM Extra Thin Hydrocolloid Dressing). The N95 models evaluated were the semi-rigid cup-style 1860/1860S (3 M), the flat-fold-style BYD N95 (BYD Care, Los Angeles, CA), the duckbill-style BSN medical ProShield N-95 (BSN Medical, Mount Waverley, Victoria, Australia), and the 3-panel flat-fold-style Aura 9320 Ap (3 M). The use of the hydrocolloid dressing significantly reduced the fit for the non-rigid type N95s (the vertical flat-fold and duckbill styles) but did not significantly reduce the fit of the cup-style and 3-panel flat-fold style. The fit factor ranges for the vertical flat-fold style were 109–201 (control) and 20–201 (with dressing). The FF ranges for the duckbill style were 100–201 (control) and 20–201 (with dressing) (Ng et al. 2022).

Another recent study by Trehan et al. (2021) evaluated elastomeric half-mask respirator (6000 series or 7000 series, 3 M) fit with three types of skin protectants, specifically, Cavilon film, 3 M, Tegaderm film, 3 M, and a silicone scar sheet (ScarAway, Perrigo, Allegan, MI). The skin protectant model numbers were not specified in their publication.

Compared to the control condition, there were no statistically significant differences in overall fit factor when using either the Cavilon film or Tegaderm film; however, the silicone scar sheet FFs were significantly reduced compared to the control condition (Trehan et al. 2021).

There remains a need to further investigate how various types of skin protectants affect N95 fit. This pilot study was initiated under the null hypothesis that the application of skin protectants would not change N95 fit. This study: (1) evaluated three different N95 models; (2) collected data for multiple donnings within each test protectant condition; and (3) analyzed the quantitative fit test data (numerical fit factor result) to determine which study variables significantly affected fit factor results and passing rates.

Methods

The pilot study was conducted under a protocol approved by the University of Cincinnati's Institutional Review Board (IRB). A sample of 10 subjects (4 males and 6 females), who provided written informed consent, participated in quantitative fit testing of three N95 models with the application of three different skin protectants, as well as a control condition of no skin protectant. Manual caliper measurements of menton-sellion length (face length) and bizygomatic breadth (face width) were taken for all subjects on their first visit (Table 1). These measurements were then used to classify each subject into 1 of 10 cells according to the NIOSH Bivariate Panel, an anthropometric sizing system used to classify test subjects for respirator testing (Zhuang et al. 2007).

Three commonly used N95 models in healthcare were evaluated: Aura 1870+ (3 M), 8210/8110S (3 M), and Fluidshield (models N95-46767/46867, Kimberly-Clark (KC), Irving, TX, USA). The 3 M Aura 1870+ is a tri-fold design (one size only). The other 3 M model is cup-shaped and available in "regular" (8210) and "small" (8110S) sizes. The KC is a duckbill design available in two sizes – "regular" (46767) and "small" (46867).

Preliminary fit testing of the control condition determined each subject's best-fitting N95 size per model (for those models available in more than one size) to be worn during the evaluation using the skin protectants. Due to the 3 M Aura 1870+ being available in one size only, all subjects were assigned this available size. For the N95 models available in two sizes (3 M 8210/8110S and KC 46767/46867), subjects in panel cells 1–5 were initially tested in the "small" model size, and subjects in panel cells 6–10 were tested in the "regular" model size. Three fit tests were performed with the initially selected size. If the subject passed two of three fit tests, the initial size was kept for the remainder of the study. If the subject could only pass one of three tests or failed all three tests in the initial size, then the subject performed three additional fit tests using the alternative size. If the subject passed two or three fit tests with the alternative size, the alternative size was kept for the remainder of the study. If the subject failed all three fit tests in the alternative size or could only pass one fit test with the alternative size, then the subject was assigned the FFR size (either "small" or "regular") which achieved the highest single fit factor amongst the two sizes. Following this procedure, all subjects were assigned the 3 M 8210 ("regular" size) and only two of the 10 subjects were assigned the Kimberly Clark "small" size (Table 1).

For a subject to have been included in the study, they had to initially pass one quantitative fit test under the control condition (no application of a skin protectant) on at least one of the three N95 models. It is important to acknowledge that the study aimed to determine how fit was impacted by skin protectant application, including the hypothetical situation where fit might improve with the application. From this perspective, subjects could have failed all three fit tests for the control condition for as many as two of the three N95 models. This pilot study's criteria for admission into the study differs from practice in an OSHA-regulated workplace, where a respirator user must pass a fit test to use a specific respirator model.

The three skin protectants evaluated were a bandage (Band-Aid Flexible Fabric Bandage (3/4" × 3"), Johnson and Johnson, New Brunswick, NJ, USA), a surgical tape (Durapore Surgical Tape, 3 M), and a barrier cream (Cavilon Durable Barrier Cream, product no. 3355, 3 M). These skin protectant types were chosen because they are common items found in healthcare settings and are also of three different types (bandage, surgical tape, and barrier cream). The Cavilon Durable Barrier Cream product tested (product no. 3355) was not found to be recommended for use as a skin protectant to be used with respirators by 3 M (33M 2020). At the time of this writing, none of the three skin protectants in this study are recommended for use with the N95 models in this study by the FFR manufacturers. Thus, using these specific protectant/N95 combinations in the workplace would not be consistent with each N95 model's individual NIOSH respirator approvals.

Three fit tests on the same respirator were performed for each combination of subject, skin protectant, and N95 model; a brand new N95 FFR was used for each test combination. The control condition was tested first for all subjects. The three skin protectant applications were then randomized for testing. Males were instructed to arrive for testing with shaven faces, but all subjects, both male and female, were not instructed to remove any applied facial products or makeup or wash their faces prior to testing.

Skin protectants were self-applied by the subjects to the vulnerable areas on their face related to pressure-induced injury: the nose bridge and cheek areas (demonstrated on manikin heads, Figure 1). For the barrier cream, a droplet ~5 mm diameter was squeezed onto a sterile, 100% cotton round wipe for facial application. The barrier cream was applied prior to performing the first fit test and additional cream was not applied between fit tests. The respirator sealing surface was not wiped between fit tests. After the three fit tests were completed, the subject wiped their face with a clean round wipe. Because the subjects wiped their faces following the third fit test, it was not expected that any residual cream would affect fit test results for the bandage or surgical tape tests (if those tests were randomly selected next).

Users were allowed to don and self-adjust their N95s. Following this adjustment, the test operator verified if the respirator was correctly donned by visually inspecting the placement of the N95 on the face and the placement of the straps on the head and around the neck. A user seal check was performed prior to fit testing. A rest period of 2–3 min was given for subjects between fit tests. Fit testing was performed with a calibrated PortaCount Respirator Fit Tester (8048, TSI) operating in "N-95 mode". Daily operational checks of

the PortaCount were performed prior to subject testing. Fit testing was performed in a test chamber using supplemented sodium chloride aerosol.

The OSHA-accepted ambient aerosol condensation nuclei counter protocol was used, which consists of eight sequential exercises: normal breathing, deep breathing, turning head side to side, moving head up and down, talking (reciting the “rainbow passage”), grimacing, bending over (at the waist as if to touch the toes), and normal breathing (OSHA 1998). Passing the quantitative fit test is achieving a FF = 100 (OSHA 1998). The maximum FF output by the PortaCount in “N-95 mode” is “200+”; where “200+” resulted, 201 was recorded.

Designating FF as the dependent variable, an analysis of variance (ANOVA) was used to examine the main effect of the protectant (the three skin protectants and the control condition), the main effect of the N95 model, and the two-way interaction of the protectant and N95 model. A binomial logit model was used to explain the effect of the protectant and N95 model on the ability to pass the fit test (achieve a FF = 100). Statistical tests were performed using R (The GNU Project).

Results

For FF passing rate data aggregated across all tested N95 models, the control condition (pass rate 74%) had the highest passing rate followed by the conditions of Cavilon barrier cream (pass rate 66%), Durapore (47%), and Band-Aid (44%). Binomial logit model results revealed that, compared to the control condition, using Band-Aid decreased the odds of passing the fit test by 76.7% ($p < 0.001$) across all respirator models. Durapore decreased the odds of passing the fit test by 74.2% ($p < 0.001$) compared to the control condition. Additionally, compared to the control condition, using Cavilon decreased the odds of passing the fit test by 37.4% across all models; however, the probability of passing a fit test was not statistically significantly different from the control condition ($p = 0.174$).

Table 2 summarizes fit test outcomes (pass or fail) by protectant (including the control condition of no protectant)/N95 model combination. Within each protectant category (including the control condition), the 3 M 8210 had the highest passing rate compared to the 3 M Aura 1870+ and KC models. For the control condition, the 3 M Aura 1870+ and KC models had the same passing rate of 63%. For the protectant conditions, the passing rates for the 3 M Aura 1870+ and KC models varied somewhat, with the largest difference being for the Band-Aid condition (pass rates: 3 M Aura 1870+ (40%), KC (17%)).

Figure 2 presents mean FF data by N95 model and protectant. For each of the N95 models, mean FFs were highest under the control condition. The main effects of the protectant and N95 model were both significant (p -values < 0.001); additionally, their interaction was significant ($p = 0.02$), indicating that fit is affected by the combined effects of the skin protectant and N95 model. The same significant effects were observed for running a mixed model effects ANOVA, with the effect on subject ID within the interaction of protectant and model to account for subject effects.

For mean FF data aggregated across respirator models, the highest mean FF was observed for the control condition (mean = 145, standard error (SE)=6.4). Using post-hoc, Bonferroni adjusted two-sided pairwise comparisons, Cavilon (mean = 124, SE = 6.9) not statistically significantly different from the control; however, both Band-Aid (mean = 99, SE = 7.6) Durapore (mean = 101, and SE = 7.4) differed statistically significantly from the control ($p < 0.001$). For the 3 M 8210 N95 model, mean FFs across all protectant types were not statistically significantly different from the control. For the 3 M Aura 1870+, Cavilon did not statistically significantly differ from the control, however, both Band-Aid and Durapore did. For the KC model data, only Band-Aid was statistically significantly different from the control.

Discussion

Based on the ANOVA results for aggregated data of the N95 models and protectants, the null hypothesis that the application of skin protectants would not change N95 fit is rejected. The individual and combined effects of the N95 model and protectant were found to be significant for the outcome variable FF. The results of the post-hoc ANOVA tests show that the fit of each N95 model was affected differently by protectant type when compared to the control condition of no protectant. These results support evaluating the fit of a respirator while wearing a skin protectant prior to use in the workplace. Users should consult the respirator manufacturer for guidance on the use of skin protectants for their specific respirator model.

Because this pilot study only included 10 test subjects and three types of skin protectants, it is difficult to draw direct comparisons of the results to those of the previous skin protectant fit test studies. Additionally, the three N95 models selected for this pilot study were not included in the previous studies. However, one general comparison can be made—the previous N95 fit test studies that included Cavilon liquid advanced skin protectant and Cavilon barrier film (Guschel et al. 2020; Bui et al. 2021), along with this study using Cavilon barrier cream, suggest that barrier creams, films, and liquid skin protectants have less impact on N95 fit compared to the other skin protectants evaluated. Similar to this study, Ng et al. (2022) observed that the effect on fit can be N95 model dependent when applying a skin protectant, although only one hydrocolloid dressing was evaluated.

Some limitations of this pilot study include only evaluating three respirator models and three skin protectant types. Additionally, the study had a small number of subjects (10), and the study population was not heterogeneous. The subjects did not fill all 10 cell sizes of the NIOSH Bivariate Panel, and at most, only two subjects filled select cells. These limitations were due to the urgency to conduct this study at the height of the COVID-19 pandemic. Additionally, subjects were not asked to remove any facial products (e.g., lotions or makeup) or wash their faces prior to beginning testing. Last, this study did not evaluate the ability of the different protectants to mitigate facial tissue conditions caused by extended respirator wear times.

Conclusions

This pilot study's findings indicate that the N95 model, skin protectant type, as well as their combined effects, are significant for the outcome variable FF. Across all N95 models, the barrier cream had the least negative impact on FF and the odds of passing a fit test compared to the surgical tape and bandage protectants. If a skin protectant is to be worn with a tight-fitting respirator, the fit of the respirator should be evaluated with the skin protectant applied before use in the workplace.

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Data availability statement

The data that support the findings of this study will be made available through the NIOSH Data and Statistics Gateway following NIOSH clearance.

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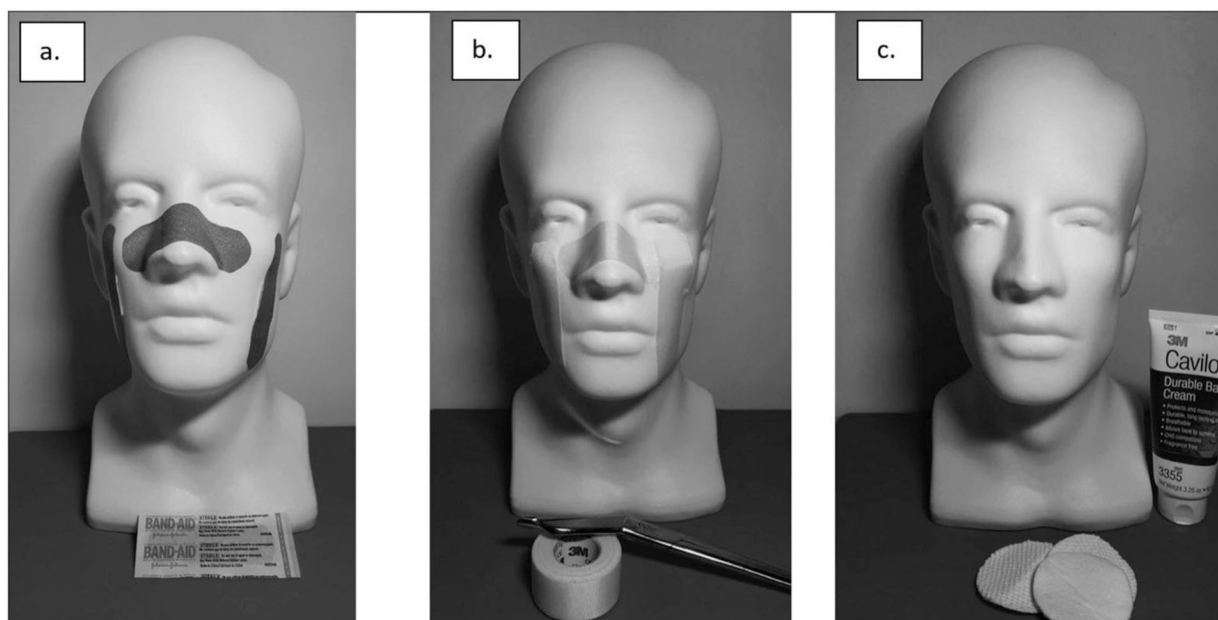


Figure 1. Skin protectants shown applied to nose bridge and cheeks. (a) Band-Aid Flexible Fabric bandage (3/4" × 3", Johnson and Johnson, New Brunswick, NJ, USA); (b) Durapore surgical tape (1" wide, 3 M, St. Paul, MN, USA); and (c) Caviol Durable barrier cream (product no. 3355, 3 M).

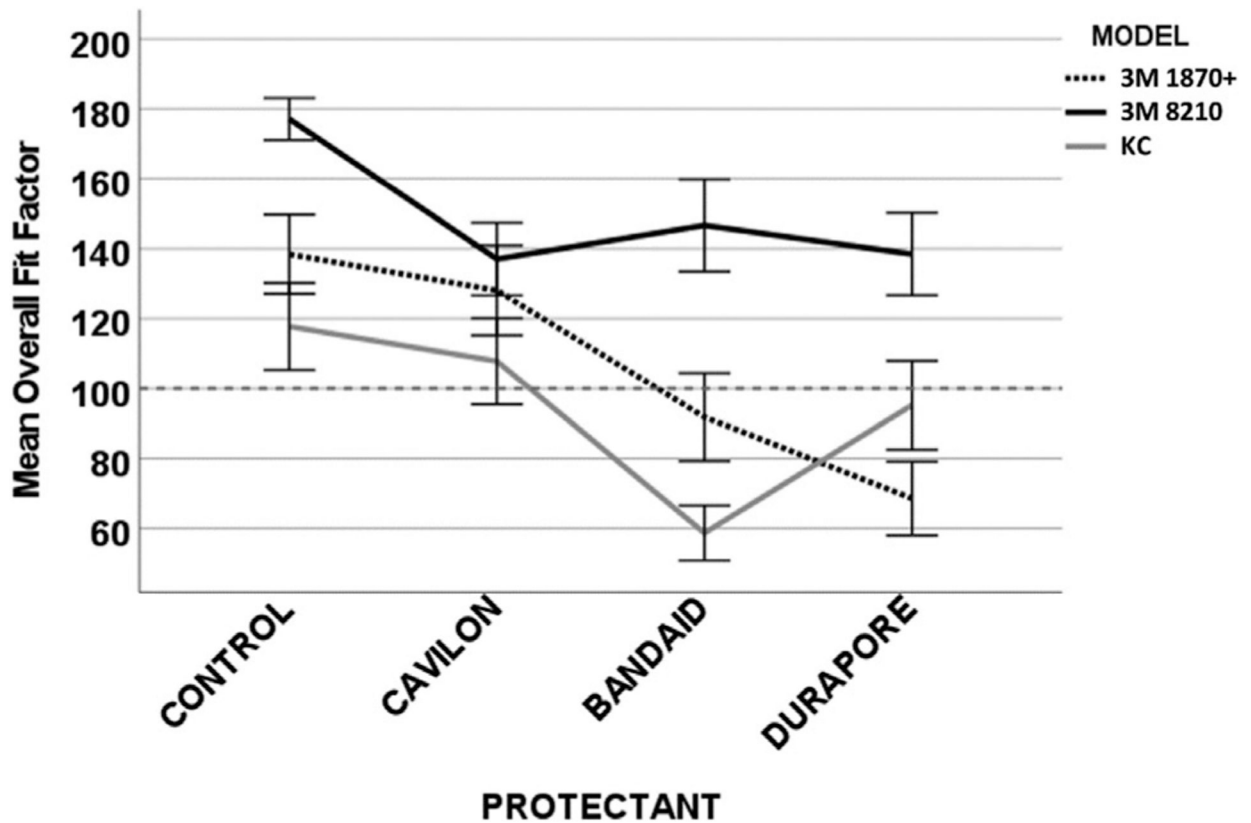


Figure 2. Plot for the two-way interaction between protectant and N95 model.

Notes: 1. Horizontal dotted line at 100 depicts the Occupational Safety and Health Administration's required passing fit factor (FF >100) for FFR use in occupational settings (29 CFR 1910.134).

2. Protectants: Cavilon Durable Barrier Cream (product no. 3355, 3M); Band-Aid Flexible Fabric Bandage (3/4" × 3", Johnson and Johnson); Durapore Surgical Tape (1" wide, 3M).

3. N95 Model Styles: 3M Aura 1870+ (tri-fold shape); 3M 8210 (cup shape); KC (duckbill shape).

Table 1.

N95 FFR size assignment^A.

Subject ID	NIOSH Bivariate Cell	Face Width (mm)	Face Length (mm)	Gender	Race	KC ^B Size Assigned
1	7	135	127	Male	Caucasian	Regular
2	4	142	118	Female	Caucasian	Regular
3	7	138	127	Male	Caucasian	Regular
4	1	127	106	Female	Asian	Small
5	6	128	123	Male	Caucasian	Regular
6	9	141	132	Female	Caucasian	Regular
7	6	132	129	Female	Caucasian	Regular
8	9	144	136	Male	Caucasian	Regular
9	1	124	105	Female	Caucasian	Small
10	4	136	117	Female	Caucasian	Regular

^A All subjects were assigned 3 M 8210 (“regular” size) and 3 M Aura 1870+ (one-size only).

^B Kimberly Clark Fluidshield models N95-46767 (“regular” size)/46867 (“small” size).

Table 2.

Descriptive statistics for fit factor (FF).

Protectant	N95 Model	n (Fit Tests) ^C	Pass Rate (%)	Fit Test Outcome (Pass or Fail) ^D		n (Fit Tests by Outcome)	Mean (FF)	Standard Error of the Mean
				Pass	Fail			
Control (no protectant)	Aura 1870+	30	63	Pass	Fail	19	180	7
				Pass	Fail	19	180	7
	8210 ^A	30	97	Pass	Fail	29	180	6
				Pass	Fail	1	98	--
Cavilon Barrier Cream	KC ^B	30	63	Pass	Fail	19	162	10
				Pass	Fail	11	42	6
	Aura 1870+	30	67	Pass	Fail	10	42	8
				Pass	Fail	20	171	9
Band-Aid Flexible Fabric Bandage	8210 ^A	30	77	Pass	Fail	7	52	9
				Pass	Fail	23	163	7
	KC ^B	30	53	Pass	Fail	14	43	5
				Pass	Fail	16	165	8
Durapore Surgical Tape	Aura 1870+	30	40	Pass	Fail	18	41	6
				Pass	Fail	12	168	8
	8210 ^A	30	77	Pass	Fail	7	30	8
				Pass	Fail	23	182	7
	KC ^B	30	17	Pass	Fail	25	42	4
				Pass	Fail	5	141	13
	Aura 1870+	30	33	Pass	Fail	20	31	4
				Pass	Fail	10	144	7
	8210 ^A	30	70	Pass	Fail	9	50	9
				Pass	Fail	21	176	6
	KC ^B	30	37	Pass	Fail	19	47	6
				Pass	Fail	11	179	8

^A All 10 subjects tested the 3 M 8210, thus there is no data reported for 3 M 8110S.

^B Aggregated data for two Kimberly Clark Fluidshield sizes: eight subjects tested “regular” (46767), and two subjects tested “small” (46867).

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C_{30} fit tests = 10 subjects \times 3 fit tests on the same physical FFR sample for each subject.
 $D_{Passing}$ is achieving FF 100 as specified by the OSHA Respiratory Protection Standard (29 CFR 1910.134).