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Effect of Skin Protectants on the Total Inward Leakage of N95 Respirators: Testing with an Advanced Static Headform

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ABSTRACT

The COVID-19 pandemic introduced considerable challenges for respiratory protection of different population groups. Disposable medical masks and NIOSH-approved N95 filtering facepiece respirators (FFRs) are typically their only defense against the virus. At the same time, continuous wearing of these devices, especially some N95 FFR models cause damage to the facial skin, such as skin irritation, swelling, and scaling. Skin protectants are becoming increasingly popular and effective in providing a protective barrier for the skin that reduces direct contact between a wearer's face and respirator. Recent pilot studies involving human subjects have examined the effect of skin protectants on the performance of respirators/masks through fit testing, but their findings are heavily impacted by between-subject variability. This investigation deployed a standardized protocol that utilized the NIOSH advanced static manikin headform connected to a Breathing Recording and Simulation System (BRSS), producing a predetermined breathing pattern. The effect of skin protectants on the total inward leakage (TIL) was evaluated for three N95 FFR models, five different skin protectants, and two breathing flow rates. The aerosol particle concentrations inside and outside the respirator were measured with NaCl serving as the challenge aerosol. The TIL was shown to be significantly affected by the interaction of the skin protectant type, breathing flow rate and FFR models. The data suggest that different skin protectants may influence the performance of disposable N95 FFRs in different ways - by either increasing or decreasing the TIL value relative to one with no skin protectants applied. No negative effects on the TIL was observed for either tape- or gel/cream-type protectants when testing with 3M 8210 or 3M 1870+ FFRs; however, the use of skin protectants of either group with the AOSafety 1050 FFR may compromise its performance as quantified by the TIL.

Keywords: N95 respirator, Skin protectant, Total inward leakage (TIL), Manikin, Breathing simulator

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1 INTRODUCTION

As COVID-19 is sweeping the world, hundreds of millions of people wear respiratory protective devices in various occupational and non-occupational environments. The N95 filtering facepiece respirators (FFRs) approved by the National Institute for Occupational Safety and Health (NIOSH) have been in a particular demand. Millions of healthcare workers (HCWs) worldwide who are exposed to high levels of SARS-CoV-2 need to be adequately protected against the virus. However, wearing N95 FFRs for a long time may cause dents, swelling and other impairments of the facial skin. Skin dryness/tightness and scaling are among the most common symptoms (Kelechi *et al.*, 2020; Lan *et al.*, 2020; Bui *et al.*, 2021). The use of skin protectant aims at providing an effective protective barrier for the skin to reduce or avoid direct contact with FFRs. Skin protectants applied to the bridge of the nose and cheeks are known to reduce skin irritation and damage (Smart *et al.*, 2020; Bui *et al.*, 2021). While barrier cream, surgical tape, bandages, and other protectants are capable of reducing the friction and pressure on the facial skin by the N95 FFRs, limited data is available on their effects on the FFR performance (the degree of protection offered by the device).

Recent studies have evaluated the effect of skin protectants on the fit factor of respirators/masks worn by human subjects (Guschel *et al.*, 2020; Bergman *et al.*, 2021; Ng *et al.*, 2021; Trehan *et al.*, 2021). However, the findings presented in these reports were affected by the individual (between-subject) variability, which is associated with the differences in breathing patterns, individual face dimensions, and, probably, other factors. To determine the effect of skin protectants on overall respirator performance, alternative test protocols utilizing a standardized approach that eliminates the above variabilities should be deployed.

The Total Inward Leakage (TIL)—a measure of the respirator performance—is quantitatively defined as a ratio of aerosol concentrations measured inside the respirator to outside the respirator and expressed as a percent (Rengasamy *et al.*, 2018). The TIL is used to evaluate the performance of respirators given three particle penetration pathways: through the filter media, faceseal interface and exhalation valve, if present (CDC, 2019).

The present effort aimed at determining the TIL of NIOSH-approved disposable N95 FFRs when skin protectants of different types were applied. The TIL values obtained with and without skin protectants were compared. The study was conducted using an advanced static headform as a key element of the manikin-based study design.

2 METHODS

2.1 Experimental Design

This study was conducted in a 24-m^3 aerosol exposure chamber. An advanced static headform with a facial length of 124.5 mm and width of 126 mm was used. These dimensions fall into Zone 6 (medium sizes) according to the NIOSH Bivariate panel (Bergman *et al.*, 2015). The headform was made of soft elastic silicone material which was developed to imitate natural skin elasticity. The material is chemically neutral and does not interact with components of most skin protectants. The headform was connected to the Breathing Recording and Simulation System (BRSS, Koken Ltd., Tokyo, Japan), containing an electromechanical drive and two air cylinders, to simulate a sinusoidal breathing pattern of a human by adjusting the flow rate and the breathing frequency. When the electromechanical cylinder moved back (inhalation duration, half cycle) and forth (exhalation duration, half cycle), a sinusoidal air flow was generated (Haruta *et al.*, 2008). Two cyclic flows with mean inspiratory flow (MIF) rates of 30 and 85 L min^{-1} and a breathing frequency of 0.25 Hz (15 breaths min^{-1}) and 0.42 Hz (≈25 breaths min^{-1}), respectively, were regarded as reasonable approximations of two common breathing conditions representing the moderate and strenuous workloads (Janssen *et al.*, 2005).

The following five different types of commonly used skin protectants were applied on the headform:

- Band-Aid® Flexible Fabric Bandage (3/4" × 3") (Johnson & Johnson, New Brunswick, NJ),
- Spider-Tech Medical Tape (SpiderTech USA Inc., Stafford, CT),
- Extra Thin Hydrocolloid Dressing (Model 187955, DuoDERM® ConvaTec, Oklahoma City, OK),
- Cavilon™ No Sting Barrier Film (Model 3343, 3M Corp., Saint Paul, MN), and
- Cavilon™ Durable Barrier Cream (Model 3355, 3M Corp.).

The first two represent the fabric tape-like protectants while the last three utilize a non-solid composition such as dressing, gel or cream. The latter refer to as gel/cream-like protectants. Tests were also performed without a skin protectant representing a control condition.

The following three N95 FFR models were evaluated: 8210 (3M), 1870+ (3M) and 1050 (AOSafety, Indianapolis, IN). The respirator models were selected to represent different designs. The 3M 8210 is cup-shaped, with “Regular” respirator size; and the 3M 1870+ is a tri-fold design, also with “Regular” respirator size. The AOSafety 1050 utilizes a large surface area pleated filter design available in the “Small/Medium” respirator size. These respirator sizes were selected to fit the manikin dimensions, which, as mentioned above, represent the medium size range.

The sodium chloride (NaCl) polydisperse aerosol that served as the challenge aerosol was generated in the chamber with a particle generator (Model 8026; TSI Inc., Shoreview, MN). A period of 15–20 minutes of continuous generation allowed us to establish the background aerosol particle concentration within a range of 8,000–12,000 particles per cm^3. The geometric mean aerodynamic diameter (d_a) of the particle size distribution was approximately 0.1 µm, and the geometric standard deviation (σ_g) was approximately 2.9.

A PortaCount Respirator Fit Tester (Model 8048, TSI Inc.) utilizing the condensation nuclei counting (CNC) principle was used to test the aerosol particle concentrations inside and outside the respirator under the cyclic flow condition. The instrument operated in the entire generated particle size range, without deploying an N95 Companion mode. The Companion utilizes an electro-mechanical method to challenge a respirator with particles of a narrow size range, which is assumed to be relevant primarily to the face seal rather than the filter. While an N95 Companion is useful for the respirator fit testing, operating in a "Companionless" PortaCount mode is more appropriate for comparing different types of respirators over a wide range of particle sizes. Also, we intended to generate a database that could be compared to other published TIL studies that have been typically conducted with an N95 companion mode turned off, e.g., Rengasamy *et al.* (2015) and (2018). The outside sampling was conducted with a 3-mm diameter probe positioned in the breathing zone, 5 cm from the center of the respirator. To sample from the inside of the respirator, a N95 Fit Test Probe Kit (Model 8025-N95, TSI Inc.) was used with the same 3-mm probe positioned between the nose and upper lip of the manikin. The sample duration was 45 s.

Each test with a PortaCount attached to a respirator-wearing manikin generated seven TIL values in a row. With three replicates, we generated 21 values per set of conditions, and recorded the calculated mean value.

The TIL value was determined in each test as the ratio of the particle concentrations measured by the PortaCount inside and outside the respirator. A total of 756 pairs of the inside and outside aerosol concentration values were obtained. This accounts for two MIF rates, six protectant conditions (including control), three N95 FFRs models, and 21 replicates.

2.2 Data Analysis

Data analysis was performed using IBM SPSS Statistics version 23 (IBM Inc., Armonk, NY) and Microsoft Office Excel (Microsoft Corp., Redmond, WA). Three-way analysis of variance (ANOVA) was conducted to evaluate the effects of skin protectants, MIF, and FFR model, and their interactions on the TIL. A two-tail t-test and one-tail t-test were performed to examine the statistical significance of differences between specific sets of conditions. P-values below 0.05 signified significant differences.

3 RESULTS

3.1 ANOVA – Summary of Results

The test results analyzed via a three-way ANOVA are presented in the Table 1. It was revealed that factors such as presence of a skin protectant, breathing regime (determined in this effort as the MIF at a specific breathing frequency), and FFR model, significantly ($p < 0.001$) affected the TIL. The interactions between two factors, i.e., skin protectants and MIF (skin protectants * MIF), skin protectants and FFR model (skin protectants * FFR model), and MIF and FFR model (MIF * FFR model) were also found to be significant in affecting the TIL ($p < 0.001$).

Additionally, the interaction among the three factors—a skin protectant, MIF, and an FFR model—was found to be of strong significance in affecting the TIL ($p < 0.001$). This means that

Table 1. Three-way ANOVA results.

Source	Sum of Squares	Degree of freedom (df)	Mean Square	F value	P value
Skin Protectants	1.114	5	0.223	7.352	< 0.001
MIF	64.816	1	68.816	2271.227	< 0.001
FFR Model	54.227	2	27.114	894.886	< 0.001
Skin Protectants * MIF	9.577	5	1.915	63.216	< 0.001
Skin Protectants * FFR Model	19.166	10	1.917	63.257	< 0.001
MIF * FFR Model	37.390	2	18.695	617.027	< 0.001
Skin Protectants * MIF * FFR Model	6.850	10	0.685	22.608	< 0.001

at least one of the three-way interactions has a significant effect on the TIL change. Different combinations of these three factors affected the TIL in different ways, causing either its increase or decrease. For instance, when taking a trio of control (no skin protectant applied), 3M 8210 FFR and MIF = 30 L min^{-1} as the reference in the three-factor model, the TIL showed significant ($p < 0.05$) increase relative to the combination of 3M Cavilon Durable Barrier Cream, AOSafety 1050 FFR and MIF = 85 L min^{-1}. The other two combinations – Spider-Tech, 3M 1870+ FFR and 85 L min^{-1}, and Band-Aid, AOSafety 1050 FFR and 85 L min^{-1} – produced TIL values which are not significantly different from the TIL of the reference combination ($p > 0.05$).

3.2 Effect of Skin Protectant on the TIL Change

The TIL values obtained for three tested disposable N95 FFRs, and six skin protectant conditions under two breathing regimes (determined by MIFs) are presented in Fig. 1. The data were lognormally distributed. The TIL values are shown in the figure as geometric means and 95% confidence intervals.

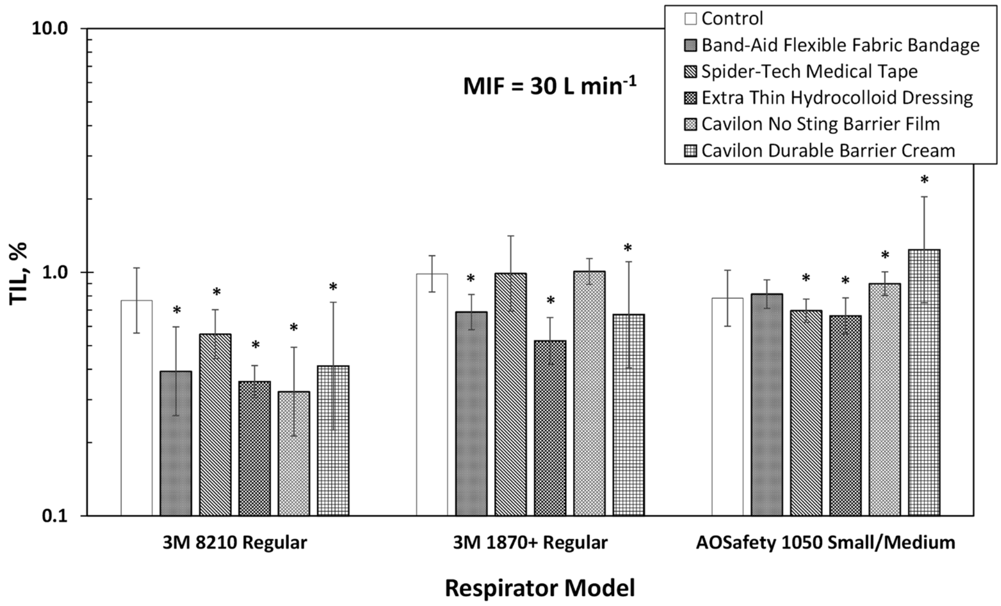
For the 3M 8210 respirator donned on the manikin breathing at MIF = 30 L min^{-1}, the TIL significantly ($p < 0.05$) decreased when a skin protectant (any of the five) was applied. At the same breathing flow rate, applying a 3M Cavilon No Sting Barrier Film on the manikin skin decreased the TIL of the 3M 8210 FFR to 0.32%, which was the lowest TIL observed among all tested skin protectants in this study. At 30 L min^{-1}, the TIL of 3M 1870+ FFR also significantly ($p < 0.05$) decreased due to the use of Band-Aid, DuoDERM Extra Thin Hydrocolloid Dressing and 3M Cavilon Durable Barrier Cream, as compared to the control group. When wearing AOSafety 1050 FFR, the use of Spider-Tech and Extra Thin results in a statistically significant ($p < 0.05$) decrease of the TIL, while Band-Aid and both tested 3M Cavilon Barriers lead to an increase in the TIL value. The analysis shows that 3M Cavilon Barriers has a significant ($p < 0.01$) effect on the TIL value, but the use of Band-Aid had no significant impact ($p > 0.05$). DuoDERM Extra Thin Hydrocolloid Dressing applied to 3M 1870+ and AOSafety 1050 FFRs produced in the lowest TIL values, respectively 0.52% and 0.66%.

At MIF = 85 L min^{-1}, the 3M Cavilon Durable Barriers yields the lowest TIL while the Extra Thin yields the highest TIL, when wearing 3M 8210 FFR. For this respirator and this flow rate, the application of each of the five tested skin protectants produce a significant ($p < 0.001$) effect on the TIL value (compared to the control group). A decrease in TIL was observed for four skin protectants and an increase was found only for one protectant. For all five tested skin protectants, a decrease in TIL was observed when testing a 3M 1870+ FFR at a flow rate of 85 L min^{-1}. This decrease was found to be statistically significant ($p < 0.05$) for three skin protectants, namely Band-Aid, Spider-Tech, and Extra Thin Hydrocolloid Dressing. The use of Band-Aid produced the lowest TIL, while 3M Cavilon No Sting Barrier Film skin protectant yields the highest TIL. However, no significant difference ($p > 0.05$) in TIL values was found between the two.

The skin protectant effect observed when testing with the AOSafety 1050 FFR was different than that obtained for the two other respirator models: all five tested skin protectants generated higher TIL values ($p < 0.05$) compared to the control group. Among them, Extra Thin Hydrocolloid Dressing generated the highest TIL.

3.3 Effect of MIF on the TIL Change

The breathing regime (determined in this effort as the MIF at a specific breathing frequency) was shown to be a significant factor influencing the TIL ($p < 0.001$), i.e., TIL measured at 30 L min^{-1} significantly differed from the TIL measured at 85 L min^{-1}. It is found that with the 3M 8210 FFR model, the TIL values were all lower for MIF = 30 L min^{-1} compared to 85 L min^{-1} (Fig. 1). This is consistent with the analysis obtained for the AOSafety 1050 FFR where the TIL values were all lower at MIF = 30 L min^{-1}. However, the tests performed with 3M 1870+ FFR did not produce such a straightforward relationship between the TIL and MIF. For this respirator and either Extra Thin Hydrocolloid Dressing or 3M Cavilon Durable Barrier Cream applied, we observed the TIL values determined at a higher flow rate were greater than those found for lower flow rate. However, for the other three skin protectants (Band-Aid, Spider-Tech, and 3M Cavilon No Sting Barrier Film), the TIL values measured at MIF = 85 L min^{-1} were lower than those measured at MIF = 30 L min^{-1}.



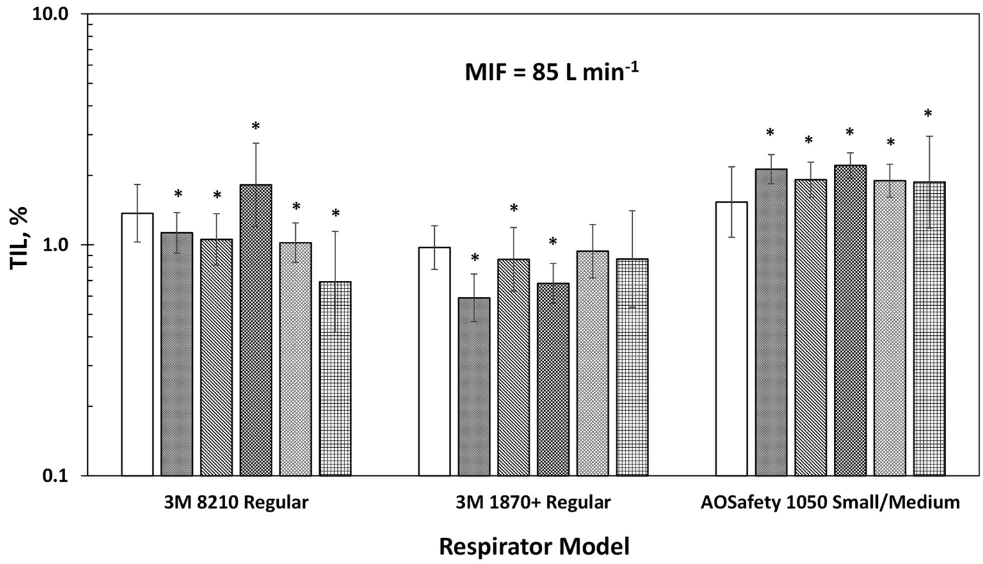


Fig. 1. The Total Inward Leakage (TIL) measured using a TSI PortaCount for three N95 FFRs donned on an advanced static manikin headform while challenged with NaCl aerosol particles under two mean inspiratory flow (MIF) rates. The bars represent TIL values determined under control condition (with no skin protectant applied) and when applying five different skin protectants. The error bars represent 95% confidence intervals of TIL values on a log-scale. An asterisk designates significant differences from the control condition ($p < 0.05$).

3.4 Effect of FFR Model on the TIL Change

The data suggest that the TIL of 3M 1870+ FFR was significantly ($p < 0.001$) different from the one obtained by the 3M 8210 FFR, while there was no significant difference between 3M 8210 and AOSafety 1050 FFRs. Different respirator models featured different TIL values when the skin protectants and MIF factors were held constant. The tests performed with the 3M 8210 FFR at MIF = 30 L min^{-1} produced the lowest TIL values regardless which skin protectant was applied and if it was applied at all (Fig. 1). For the 3M 1870+ FFR at MIF=85 L min^{-1}, application of any skin protectant reduced the TIL, compared to the control condition. The tests performed with the AOSafety 1050 FFR showed an opposite trend, i.e., the application of any of the tested skin protectant increased the TIL, comparing to the control group.

4 DISCUSSION

This study generated a large database for different skin protectants, inhalation flow rates and respirators tested. The results indicated that the interaction among skin protectants, FFR model and MIF was of strong significance in affecting the TIL value. This finding is in line with the results of Bergman *et al.* (2021), who reported that respirator fit was affected by the combined effects of skin protectant and FFR model.

The results showed that the application of the Extra Thin Hydrocolloid Dressing provided the best performance improvement for either respirator at MIF = 30 L min^{-1}. The study findings were compared to the recent reports on the role of skin protectants. While we acknowledge that the comparison of the manikin-generated TIL data with fit factor measurement results may be arguable, such a comparison appears useful for analyzing and interpreting the findings of this investigation. For example, Guschel *et al.* (2020) examined the N95 respirator's fit on two hospital staff members using four different skin protectants, including the Extra Thin Hydrocolloid Dressing. The authors reported that the application of this hydrocolloid dressing resulted in the most significant improvement of the respirator fit compared to the other tested skin protectants, which is consistent with our findings. Our data obtained with 3M 1870+ FFR and a hydrocolloid dressing were also compared to the findings of a large human subject study published by Ng *et al.* (2021). Both papers reported a significant improvement in performance of a 3-panel flat-fold style N95 FFR due to the use of a hydrocolloid dressing skin protectant.

It is acknowledged that the same skin protectant applied with different respirator models may generate opposite effects. For example, the application of the 3M Cavilon Durable Barrier Cream significantly improved the performance of two 3M FFRs, but did not enhance the performance of AOSafety 1050 FFR. We believe this difference, at least partially, reflects the differences in the contact between the peripheral area of a particular respirator and a protectant, as well as the tightness of a specific respirator model donned on the manikin.

Application of skin protectants improved the performance of 3M 8210 and AOSafety 1050 respirators at a flow rate of 30 L min^{-1}. Also, the presence of a skin protectant was shown to improve the performance of 3M1870+ FFR at 85 L min^{-1}. These findings are not in a full agreement with other reports. For instance, the recent study of Bergman *et al.* (2021) examining the performance of N95 respirators on human subjects while using three different skin protectants (bandage type, medical tape and barrier cream), reported a decrease of the efficiency of N95 FFRs compared to the control group (subjects using no skin protectants). Bui *et al.* (2021) also observed that the use of skin protectants may interfere with the N95 respirator fit. This difference may be, at least, partially attributed to the fact that the quoted studies involved various head movements while the present study was conducted with a static manikin headform. Additionally, the different face dimensions of the tested human subjects in the quoted studies affected the outcomes whereas the present investigation was conducted with a fixed headform design. Thus, the differences may also be associated with the between-subject variability – a complicated factor limiting almost any investigation involving human subjects.

Our study results also suggest that for the same respirator, the change in MIF produces different effects in terms of how a skin protectant influences the TIL. For example, for the 3M 1870+ FFR, the skin protectant application reduced TIL at 85 L min^{-1} but did not do the same at 30 L min^{-1} as compared to the control group. To interpret this finding, further studies should be performed at various breathing regimes.

Two 3M Cavilon skin protectants were found to decrease the TIL values in both tested 3M FFRs, with one exception: 3M Cavilon cream combined with 3M 1870+ tested at 30 L min^{-1}. Similarly, Trehan *et al.* (2021), who evaluated the fit of 3M half-mask respirators with different skin protectants, reported that Cavilon barrier significantly increased the barrier seal, thus improving the respirator performance.

In addition, the reported TIL data was divided into three groups, namely control, tape-like skin protectants (two protectant types integrated), and gel/cream-like skin protectants (three protectant types integrated). The data suggest that the use of tape-like skin protectants as a test group significantly ($p < 0.05$) decreased the TIL values compared to the control group at MIF = 30 L min^{-1} for the two tested 3M respirators. A non-significant ($p > 0.05$) decrease of the TIL values was found when applying the tape-like skin protectants as a group at the same MIF for the AOSafety FFR. When applying the same skin protectants at the MIF = 85 L min^{-1}, a significant ($p < 0.05$) decrease of TIL values was observed for the both tested 3M respirators, but a significant ($p < 0.05$) increase was found for the AOSafety 1050 FFR. Meanwhile, the application of gel/cream-like skin protectants as a group significantly ($p < 0.05$) decreased the TIL values compared to the control group at both MIF for the two tested 3M FFRs, but significantly ($p < 0.05$) increased the TIL values for the AOSafety respirator. Therefore, it was concluded that deployment of skin protectants of both groups (tape- and gel/cream-type) did not negatively impact the performance of either 3M 8210 or 3M 1070+ FFRs (furthermore, it made the TIL to decrease); however, the skin protectants of either group cannot be recommended for use with the AOSafety 1050 FFR. We acknowledge that the above practical outcomes are limited to the conditions and parameters tested in this study.

5 CONCLUSIONS

This manikin-based standardized study provides evidence that the application of skin protectants may have significant implications for the performance of disposable N95 FFRs as quantified by the TIL. The study results suggest that different skin protectants may affect the respirator performance in different ways – by either increasing or decreasing the TIL value. The Extra Thin Hydrocolloid Dressing applied with either respirator generates the highest decrease of the TIL at MIF = 30 L min^{-1} as compared to controls. The TIL change was demonstrated to depend on the respirator model and breathing flow rate. Additionally, the interaction among three factors (skin protectants, MIF and FFR model) was found to be of strong significance in affecting the TIL value. Generally, we did not observe any major negative effects of the tested skin protectants of either tape- or gel/cream-type on the respiratory protection offered by the 3M 8210 or 3M 1870+ FFRs; however, the use of skin protectants of either group with the AOSafety 1050 FFR may compromise its performance as quantified by the TIL.

6 LIMITATIONS

The advanced static headform used in this study is a state-of-the art piece of equipment custom-built for NIOSH and utilized in multiple research efforts for evaluating respirators. However, a manikin-based study protocol has limitations. A stationary manikin headform is unable to mimic human activities such as head and body movements, speech, or facial expressions. These activities could affect the TIL value. In addition, even the most sophisticated headform may not fully simulate an interaction between a skin protectant and a human skin.

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