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Comparing the quantitative fit-testing results of half-mask respirators with various skin barriers in a crossover study design: a pilot study

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SUMMARY

Background: Clinicians around the world are experiencing skin breakdown due to the prolonged usage of masks while working long hours to treat patients with COVID-19. The skin damage is a result of the increased friction and pressure at the mask—skin barrier. Throughout the COVID-19 pandemic, clinicians have been applying various skin barriers to prevent and ameliorate skin breakdown. However, there are no studies to our knowledge that assess the safety and efficacy of using these skin barriers without compromising a sufficient mask—face seal.
Aim: To conduct the largest study to date of various skin barriers and seal integrity with quantitative fit testing (QNFT).
Methods: This pilot study explored whether the placement of a silicone scar sheet (ScarAway®), Cavilon™, or Tegaderm™ affects 3M™ half-face mask respirator barrier integrity when compared to no barrier using QNFT. Data were collected from nine clinicians at an academic level 1 trauma centre in New Jersey.
Findings: The silicone scar sheet resulted in the lowest adequate fit, whereas Cavilon provided the highest fit factor when compared to other interventions ($P < 0.05$).
Conclusion: These findings help inform clinicians considering barriers for comfort when wearing facemasks during the COVID-19 pandemic and for future pandemics.
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Introduction

Throughout the COVID-19 pandemic, many healthcare clinicians are required to use facemasks for protection. Due to

mask shortages, many clinicians choose to wear their own personal protective equipment (PPE), including 3M™ half-face mask respirators. Both the Joint Commission as well as the American College of Emergency Physicians have endorsed the use of self-obtained PPE by clinicians [1,2]. N95 respirators, currently cleared in phase 4 by the Food and Drug Administration (FDA), are both labelled and recommended by the Centers for Disease Control and Prevention as single-use masks [3,4]. Unfortunately, clinicians are wearing masks for extended

periods and are reusing the N95 and 3M half-face mask respirators across multiple shifts due to PPE shortages [5]. As a result, clinicians are experiencing skin irritation, breakdown, and ulcerations due to protracted use of N95s [6].

Before the COVID-19 pandemic, researchers viewed clinician mask discomfort from various angles, including facemask ventilation side-effects. Previous three-dimensional scanning of respirator facemasks predicted that prolonged use of these masks would cause skin damage at the nasal bridge due to increased point-of-force contacts [7]. Additionally, this work found that many attempts to reduce the discomfort at the nasal bridge of these masks may cause significant impediment to the seal of the respirator [8].

More recently, during the initial wave of the COVID-19 pandemic, researchers used social media, clinician anecdotes, and cross-sectional studies to garner information about healthcare workers' skin breakdown [9–11]. A cross-sectional study with 51 clinicians found that 38.2% of the participants failed the qualitative fit test with their dome-shaped or duckbill N95 respirators [5]. Additionally, after surveying 542 healthcare workers in China, Lan *et al.* found that 97% of clinicians reported skin damage from PPE and highlighted the nasal bridge as the most common area of skin breakdown [12]. Additionally, recent reports from the *New York Times* and broadcaster CNN highlight the general public's issue with skin breakdown, with headlines such as 'Maskne is the new acne' [10,13].

Various researchers have proposed, without conducting studies, different mask barrier solutions to prevent skin breakdown, including the use of various dressings, which indicate an acute need and an interest in this field [14–16]. In an informal effort to gather preliminary data, an e-mail questionnaire, receiving 45 responses, found that clinicians were experimenting with the hospital-recommended option of Cavilon™ as well as silicone scar sheet and Tegaderm™ to reduce friction between their face and their N95 respirator. Thus, clinicians are experiencing discomfort due to prolonged respirator use, and could be following recommendations for dressings without rigorous studies on their compromise of the face–mask seal.

The efficacy of the mask's barrier function can be measured by both qualitative and quantitative testing. Evidence suggests that quantitative fit testing (QNFT) is a more accurate and objective measurement of fit compared to qualitative fit testing (QLFT) [17–19]. Once clinicians pass either QNFT or QLFT to ensure their barrier is suitable and safe, they perform a fit check each time they subsequently don their respirator. Prior research indicates that this 'fit check method' inaccurately indicates a mask's fit 18–31% of the time [17–19]. Thus, quantitative measures are of great value and were chosen for our pilot study. More specifically, the overall fit factor from QNFT was chosen *a priori* as the primary outcome in this study.

Other researchers in this field have also shown a specific interest in using qualitative and quantitative measures of fit to study the effects of various skin dressings on the face–mask seal. A Canadian study by Lansang *et al.* measured the fit test results both quantitatively and qualitatively of healthcare workers after applying various skin barriers [20]. However, their study was limited to three participants and lacked statistical analysis on the quantitative results. Of note, similar studies in the literature have used non-validated tests or unrelated outcomes to assess masks' fit factors, such as oxygen saturation, or have focused on solutions to prevent patient, rather than clinician, skin breakdown [16,21–23].

Considering the COVID-19 pandemic, and future airborne pandemics, we chose to quantitatively investigate potential solutions that maintain clinician comfort and mask compliance without compromising safety.

Methods

Participants

This pilot study was conducted in September 2020 at a medical school affiliated with an academic level 1 trauma centre in central New Jersey. Nine clinicians were enrolled, including physicians, physician assistants, nurses, and technicians. The exclusion criteria for the pilot study consisted of individuals aged <18 years, who had an inability to wear masks due to pre-existing conditions or anxiety, who had known allergies to mask or skin dressing materials, and who were included in populations requiring special consent. Participants experiencing flu-like or COVID-like symptoms were also ineligible for this study.

Clinicians of varying ages who had their own 3M 6000 series or 3M 7000 series half-face mask respirator were recruited (Table I). 3M half-mask respirators were of interest because they were already being used by clinicians clinically, are reusable, and are readily available. Of note, the clinicians under investigation had already passed QLFT with their personal 3M half-face mask respirator that was used in the study. Furthermore, destruction of N95 respirators for use with QNFT seemed irresponsible when there was a critical supply shortage during the pandemic.

Study materials

In order to accurately assess the participant's fit factor, the TSI Incorporated PortaCount® Plus Model 8038 was used to quantitatively calculate each participant's results with their personal 3M respirator. The 3M half-face mask respirators were attached to the PortaCount Plus Model 8038 via a 3M Model 601 Quantitative Fit Test Sampling Adapter and 3M 2091(P-100) filters were used for all participants. Additionally, Cavilon, Tegaderm, and silicone scar sheet (ScarAway®) were used as the skin barrier interventions in this pilot study.

Study design

Using a cross-over study design, all participants were randomized to the order of testing between wearing their 3M

Table I
Demographic characteristics of study participants (N = 9)

Gender	
Male	7 (77.8%)
Female	2 (22.2%)
Age (years), median (IQR)	30 (30–44)
Mask size	
Small	1 (11.1%)
Medium	6 (66.7%)
Large	2 (22.2%)

IQR, interquartile range.

half-face mask respirator with no barrier, Cavilon, Tegaderm, and silicone scar sheet (Figure 1).

The participants were instructed to apply the supplied dressing on their nasal bridge. No further instruction was given to the participant regarding the placement of the dressing. Moreover, the study aimed to see the effects of the dressings as they would be commonly placed and used with masks in clinical use. All volunteers served as their own control as they were tested without a barrier, as well as with all the skin barriers, and were using their own 3M half-face mask respirator (Figure 1). Prior to testing, the PortaCount machine's daily check programmes were run daily including a classifier check for half-mask respirators and particle check for 1000 ambient particles per millilitre to ensure enough ambient particles were in the air for testing [24,25].

Participants were guided through the Occupational Safety and Health Administration (OSHA) protocol to quantify their fit factors during specific movements [24,26]. These movements included normal breathing, deep breathing, moving head side to side, moving head up and down, reading half of the rainbow passage aloud, grimacing (to break the mask seal), bending at the waist, and then normal breathing again. Normal breathing was repeated to quantify the impact of the grimace movement on the face—mask seal.

Participants' real-time fit factor was also measured using the PortaCount machine. The real-time fit factor allowed the research team to observe real-time graph data as subjects continued to adjust the mask to maximize the output fit factor [25]. In addition, participants changed their strap tension to alter their comfort and fit as they would in a clinical setting [27]. Thus, the real-time function provided the highest quantitative fit test measurement that one could achieve with each skin dressing. Additionally, as the numbers tended to fluctuate, the median, lowest and highest value of the range were recorded and analysed for trends across all three values.

The results of the real-time and OSHA protocol fit test scores were stored on a USB attached to the PortaCount, with each participant's information coded as a randomized number. These data were also manually entered into the data sheet on Rutgers OneDrive which is compliant according to Health Insurance Portability and Accountability guidelines [25].

The data were compiled using a standard spreadsheet application (Excel; Microsoft, Redmond, WA, USA) and were analysed using SAS/STAT (SAS for Windows, Version 9.4, Copyright 2017; SAS Institute Inc., Cary, NC, USA). The means and standard deviations for the fit factor and real-time fit data were calculated. Given that variables were right skewed, a natural log transformation was implemented, which normalized the distributions of the variables and stabilized variances.

Additionally, in order to compare the outcomes between interventions, repeated measures analysis of variance, with an exchangeable correlation structure, was used to determine differences in the outcomes between mask seal types. P-values were calculated via F-tests for the effect of seal type. If values were significant at $P < 0.05$, pairwise comparisons between treatments were examined.

The study was approved by the Rutgers New Brunswick Health Sciences IRB and all participants completed informed consent.

Results

In regard to pairwise comparison data, Cavilon provided a statistically significant ($P < 0.05$) increase in barrier seal compared to both the silicone scar sheet and Tegaderm (Tables II and III). These results can be further broken down where Cavilon superiority with respect to the other interventions was found in both the overall fit factor, and, in the case of the silicone sheet, in most of the specific movements. When considering the real-time fit test, Cavilon provided a statistically significant ($P < 0.05$) increase in barrier seal with respect to both the silicone scar sheet and Tegaderm. Additionally, we found no statistically significant difference between Cavilon and the control.

One of the participants failed the fit test with no barrier in place as well as other interventions. This participant had failing (<100) fit test scores of 12 for the control, 15 for the silicone scar sheet, and 36 for the Tegaderm, but had an overall fit factor score of 220 for Cavilon, which was a passing value. This participant was the only individual to have a failing score for the control case and the implications of these values are considered in the Discussion.
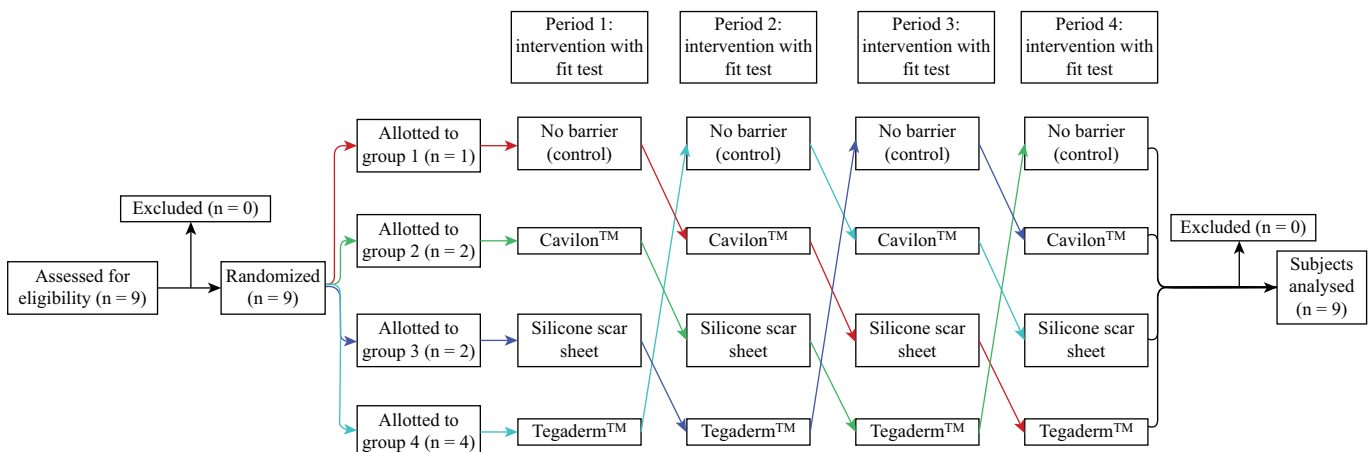

Figure 1. Study flow chart.

Table II
Differences in seals using the fit factor and real-time function (geometric mean (95% CI))

Outcome	Control	Cavilon™	Silicone scar sheet	Tegaderm™	P-value
Overall	1142.3[b] (406.2, 3219.9)	1602.0[a,c] (568.3, 4515.6)	443.1[a,b] (157.2, 1248.9)	713.2[c] (253.0, 2010.4)	0.015
Ratio after to before grimace	1.47 (1.13, 3.35)	1.59 (1.16, 4.22)	3.65 (1.52, 56.09)	3.47 (1.49, 48.08)	0.28
Deep	2757.8[b] (969.8, 7842.4)	2375.6[a] (835.4, 6755.4)	712.1[a,b] (250.4, 2025.0)	1980.7 (696.5, 5632.5)	0.082
Side to side	3363.7[b] (774.3, 14,612.0)	3096.4[a] (712.7, 13,450.9)	547.6[a,b] (126.1, 2379.2)	1216.7 (280.1, 5285.9)	0.015
Talking	620.0[b] (294.0, 1307.5)	1029.8[a] (488.3, 2171.6)	291.6[a,b,c] (138.3, 615.0)	562.1[c] (266.6, 1185.5)	0.0048
Bending	1784.0[b] (557.4, 5709.6)	2831.6[a] (884.8, 9062.5)	436.3[a,b] (136.3, 1396.5)	1135.7 (345.9, 3634.8)	0.0043
Minimum real-time (range)	1507.0[b] (485.3, 4679.8)	2394.4[a] (771.1, 7435.3)	371.2[a,b] (119.5, 1152.6)	952.8 (306.8, 2958.7)	0.011
Maximum real-time (range)	2510.7[b] (850.7, 7409.4)	5795.9[a] (1963.7, 17,104.6)	643.2[a,b,c] (217.9, 1898.5)	2132.0[c] (722.3, 6292.4)	0.0036
Median real-time (range)	2038.4[b] (689.1, 6029.4)	4218.4[a] (1426.1, 12,476.5)	513.9[a,b,c] (173.8, 1520.1)	1639.4[c] (554.2, 4849.4)	0.0047

[a,b,c,d] Pairwise differences significant at P < 0.05 if overall P < 0.05.
Superscripts indicate which pairs of treatments are independent for each seal type.

Table III
Comparison of seals using the fit factor and real-time function

Outcome	Control Mean (SD)	% change from the control: Geometric mean (95% CI)			P-value
		Cavilon™	Silicone scar sheet	Tegaderm™	
Overall	1142.3 (405.3, 3219.9)	+40.3 (−36.5, 209.5)	−61.2[c] (−82.4, −14.4)	−37.6 (−71.7, 37.8)	0.015
Ratio after to before grimace	0.39 (0.12, 1.21)	+19.3 (−76.1, 494.3)	+233.4 (−33.1, 1561.5)	+220.7 (−35.6, 1497.9)	0.28
Deep	2757.8 (969.8, 7842.4)	−13.9 (−72.1, 165.6)	−74.2[a] (−91.6, −20.4)	−28.2 (−76.7, 121.4)	0.082
Side to side	3363.7 (774.3, 14,612.0)	−7.9 (−72.7, 210.6)	−83.7[a] (−95.2, −45.1)	−63.8 (−89.3, 22.1)	0.015
Talking	620.0 (294.0, 1307.5)	66.1 (−12.5, 215.4)	−53.0[a] (−75.2, −10.7)	−9.3 (−52.3, 72.2)	0.0048
Bending	1784.0 (557.4, 5709.6)	58.7 (−40.2, 321.4)	−75.5[a] (−90.8, −35.1)	−36.3 (−76.0, 69.0)	0.0043
Minimum real-time (range)	1507.0 (485.3, 4679.8)	−37.1 (−78.7, 86.1)	−84.5[a] (−94.8, −54.2)	−60.2 (−86.5, 17.7)	0.011
Maximum real-time (range)	2510.7 (850.7, 7409.4)	−56.7 (−85.4, 28.4)	−88.9[a] (−96.3, −67.1)	2132.0 (−87.6, 9.1)	0.0036
Median real-time (range)	2038.4 (689.1, 6029.4)	−51.7 (−83.6, 42.1)	−87.8[a] (−95.9, −64.2)	−61.1 (−86.8, 14.3)	0.0047

[a,b,c,d] Significant differences from control (P < 0.05) if overall P < 0.05.
The only significant pairwise effects noted are those that are significantly different from the control.

The results of the silicone scar sheet barrier indicate a statistically significant difference between the silicone scar sheet and control for both overall and most of the specific movements in the fit factor data (Tables II and III). This difference indicates that silicone scar sheet causes a significant negative impact on the seal of the mask. These results again held true for the real-time fit test data (Tables II and III).

There was a lack of statistically significant difference between both the Cavilon and Tegaderm with respect to control for both the fit factor and real-time fit test data (Tables II and III). However, based on the small sample size and overall trend for Cavilon and Tegaderm in achieving a greater and lesser degree of seal, respectively, this lack of difference should be approached with caution. For both control and interventions, the grimace movement seemed to have no impact on the seal of the mask.

Discussion

This research aimed to determine whether there are any existing skin barriers that clinicians can apply to prevent skin breakdown on their nasal bridge without compromising the face–mask seal. Our focus was on 3M half-mask respirators due to the shortage of N95 respirators at the time. In addition, the participants' fit test was investigated quantitatively, since the QNFT is more specific and sensitive for detecting a break in the face–mask seal compared to the QLFT or the fit check [19].

Although the fit check is frequently done by clinicians prior to wearing a respirator on a shift, the test does not accurately detect a break in the respirator's seal and sometimes produces less accurate and inferior results compared to QLFT or QNFT [17,18,27]. In order to pass QLFT, clinicians must be unable to taste or smell an irritant through their facemask. For QNFTs, a PortaCount machine can be used to measure respirator fit by comparing the concentration of microscopic particles outside the respirator with the concentration of particles that has leaked into the respirator. The ratio of these two concentrations is labelled as the fit factor. A quantitative fit factor of 100 means that the concentration of particles inside the respirator is 100 times less compared with the air outside [25]. Since studies suggest that the QNFT is a superior outcome compared to QLFT, QNFT was used for this pilot study [19].

Several studies in the literature have recently investigated fit factor using skin dressings less commonly found in the USA. In addition, many publications lacked statistical analysis on their quantitative results, had small sample sizes, or measured inferior outcomes. Lansang *et al.* used both QNFT and QLFT to compare N95 respirator fit factor results without a skin dressing to results with a bland emollient, foam dressing, film dressing, and silicone cream [20]. All participants in that study passed the QLFTs with each barrier. However, one participant did not pass the QNFT with the foam dressing. Notably, this study only included three participants and lacked any statistical analysis. To our knowledge, Langsang *et al.*'s study and our study are the only two that use the PortaCount to conduct QNFT for assessing the efficacy of skin barriers in protecting the face–mask seal. Separately, Smart *et al.* investigated the effects of silicone-based dressings on the seal of N95 respirators, but this study used oxygen saturation to try to determine this outcome, which does not give any indication about the seal of the mask.

This pilot study was able to conclude that there are statistically significant differences between the various skin barriers which were found in both the overall results and in certain movements.

Even with a relatively small sample size, our results suggest that the Cavilon film provides a greater degree of seal protection when compared to other interventions. Additionally, these results indicate that Cavilon does not decrease the quality of the seal compared to a mask without a barrier. Silicone scar sheet was also found to provide the lowest level of protection and more research should be done to determine whether it (or any other barriers with similar thickness) should be applied as a skin barrier in clinical settings.

It is important to note that participants were not able to improve the results of the interventions with respect to each other when adjusting their masks using real-time data in the real-time fit test. Therefore, these results indicate that Cavilon superiority holds true regardless of method/location of application when compared to the other interventions. Additionally, the silicone scar sheet cannot be adjusted to achieve results equal to that of the control regardless of the method/application style by each participant. Although each dressing did provide varying degrees of protection, all the participants received the minimum QNFT requirements to receive a passing score (>100) with each dressing while wearing their personal 3M half-mask respirator.

One participant in our study failed the quantitative fit test while wearing Tegaderm, silicone scar sheet and no barrier. This one failure (11%) among our limited sample compares to prior research indicating a failure rate of 13% of those who had passed QLFT but did not pass QNFT [19,28]. Interestingly, while the participant failed with the control, the participant safely passed QNFT testing with the use of the Cavilon film barrier by a significant margin. This suggests that specific barriers not only protect the face–mask seal but might increase the fit factor and improve the seal. This hypothesis can also be strengthened by the overall positive scores (though not statistically significant) with respect to the control for Cavilon. Thus, further research on this specific scenario is strongly recommended.

It is understandable that researchers are trying to give advice to clinicians to help them reduce skin breakdown. Topical dressings, such as hydrocolloid dressing or silicone perforated tape over the bridge of the nose, are being recommended to healthcare workers to reduce skin damage and ulceration [14–16,29]. However, these studies are mostly based on a recommendation or qualitative analyses, which are known to be not as sensitive or specific as QNFT analyses. Clinicians need to be physically protected and comfortable when treating COVID-19 patients, and ought to follow their institutional guidelines when donning their own PPE, including respirators. Thus, it is crucial that the research community works together to use QNFT to determine which topical dressings healthcare workers can apply that will alleviate discomfort and not compromise their face–mask seal.

Our aim for this pilot study was to gain an introductory understanding on how specific skin barriers affect, if at all, the overall fit factor of the half-face mask seal. One limitation of this study is that our participant cohort was based on a small convenience sample of clinicians. We believe that this limitation was in part due to the time commitment required to do a true cross-over study (four different fit tests). Future research

should focus on increasing the sample size to garner stronger evidence with respect to which barriers clinicians can apply to protect their skin. More research is necessary to have clinicians fit-tested with only one barrier, instead of having the participant apply multiple solutions in one sitting, as QNFT is time-consuming. Another limitation of these findings is that they cannot be transferred to individuals who have not been fit-tested with a skin dressing and tight-fitting respiratory worn together, non-3M brands of half-mask respirators or single-use N95/other disposable respirators without prior fit testing.

Future studies should evaluate the effect of different skin dressing interventions on long-term clinically significant outcomes, including COVID-19 infection rates. Likewise, future studies should aim to identify barriers that not only protect skin breakdown, but also alleviate existing skin breakdown. We believe it may be beneficial to study whether disposable N95 masks are affected by any barrier methods and whether the resterilization of these masks may affect their fit factors with such barriers. Whether clinicians are wearing N95 or half-mask respirators, it is imperative to discover ways to reduce their occupational skin disease and physical discomfort without compromising the original function of these masks.

In conclusion, this pilot study indicates that Cavilon and Tegaderm may provide equal fit seal with half-face mask respirators compared to wearing the mask without a skin dressing. Additionally, the data indicate that the silicone gel tape is likely hazardous to clinicians for use with masks due to breaking the fit seal. Researchers in the field of dermatology, infectious disease, and occupational safety need to come together to ensure that our healthcare workers feel comfortable and safe when treating COVID-19 patients and other airborne diseases in the coming months and in future pandemics.

Acknowledgements

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