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Fit testing and comfort evaluation of prophylactic dressing use for healthcare workers under N95/P2 respirators in one health service district in Australia.

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RUNNING TITLE

Prophylactic Dressings under N95/P2 respirators

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Abstract

Background: This study evaluated the use of prophylactic dressings (silicone foam, silicone tape, hydrocolloid) under N95/P2 respirators to determine which dressings fit successfully.

Aim: The aim was to develop a health service protocol for one state in Australia.

Methods: Data were collected during August and September 2021 as part of the Respiratory Protection Program on 600 health workers using three types of prophylactic dressings. Five different types of respirators were used. Participant healthcare workers rated comfort on a four-point Likert scale.

Results: Successful fit was achieved by 63.6% of the respirator-dressing combinations. The best-performing respirator-dressing combination was the Trident® respirator with dressing Mepilex® Lite silicone foam (90.2% pass rate). High pass rates were found in the Trident® respirator with Mepilex® Border Lite with SofSicure silicone tape (79.1%); the 3M™ 1860 respirator with Mepilex® Border Lite with SofSicure silicone tape (74%); and the BSN orange duckbill respirator with Mepilex® Lite silicone foam (69.8%). The poorest-performing combination was the BYD™ respirator with Mepilex® Border Lite with SofSicure silicone tape (25.9% pass rate). Uncorrected chi-squared tests for association revealed significant associations between dressing type and outcome ($p=0.004$) and respirator type and outcome ($p<0.001$). Most respondents (82%) found the dressing combination markedly comfortable.

Conclusions: When using prophylactic dressings under N95/P2 respirators, it is necessary to perform a fit test. In this study Trident® respirators had the highest probability of successful fit, while BYD™ respirators had the lowest. Combining Trident® respirators with Mepilex® Lite dressing was optimal. Most participants reported greater comfort with the dressings under the respirators.

INTRODUCTION

The 2019 COVID-19 pandemic, caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has resulted globally in millions of infected cases¹ with a significant proportion of these requiring hospitalization cared for under-isolation precautions. The instigation of isolation precaution necessitates that health workers (HWs) caring for these patients wear full non-sterile personal protective equipment (PPE) or apparel, including, but not limited to aprons, gowns, respiratory protective devices, gloves, goggles and visors.² Respiratory protective devices (RPDs) are designed to protect the wearer from inhalation hazards such as airborne infectious agents and in Australia the most commonly used RPD is the disposable particulate filtering respirator (N95/P2).³

As the COVID-19 infection is through exposure to respiratory fluids carrying the virus, SARS-COV-2 warrants the use of respirators.³⁻⁶ N95 respirators are particulate-filtering facepiece respirators meeting the National Institute for Occupational Health and Safety (NIOSH) requirements for air filtration by filtering at least 95% of airborne particles (US NIOSH-42CFR84).⁵ N95 respirators and particulate filtering (P2) respirators are similar and applied interchangeably to the same conditions. Respirators have different designs and come in different sizes; therefore, not all respirators may fit as intended on all HWs.^{3,5} To ensure effective protection, a 'fit check' and a 'fit test' is needed to determine whether the selected respirator has passed.³ The respirator needs to fit firmly to ensure a quality seal,^{3,4} hence prolonged wear may result in sustained pressure on facial structures such as the bridge of the nose, cheeks and above the ears, causing unintended skin injuries, known as device-related pressure injuries (DRPI).⁷

During the pandemic, DRPIs have been reported to occur frequently in HWs⁸⁻¹¹. A cross-sectional study⁸ exploring skin reactions of 150 frontline ICU nurses in India reported a high incidence of skin damage and scarring to the bridge of the nose (77%) and behind the ears (66%) from wearing N95 respirators. Comparable results were found in a study of 61 HW in China wearing PPE for prolonged periods where a high skin reaction incidence rate (95.1%) from wearing an N95 respirator was reported,⁹ with nasal bridge scarring being very common (68.9%). A cross-sectional multicentre study of 275 HWs who wore PPE for prolonged periods reported a high (77.1%) skin reaction rate.¹⁰ Common skin reactions included burning to the face and dryness dermatitis, with a 23% rate of DRPI from respirators. The authors reported that although staff used preventative measures, such as prophylactic dressings (foam and hydrocolloid dressings) to reduce skin injury, they had little knowledge of the impact of these dressings on fit.¹⁰ An Australian observational study¹² evaluated the fit test impact of hydrocolloids under four different types of N95 respirators in 134 HWs, finding that hydrocolloid dressings affected the overall fit factors of respirators.

Our metropolitan health service in New South Wales, Australia, had implemented a stringent protocol on dressings under respirators to prevent skin injury based on a quick guide developed during the COVID-19 pandemic.¹³ However, in July 2021, HWs were advised that, until further investigation, they could not wear prophylactic dressings under respirators because of the potential break in the respirator seal. Therefore, this study was conducted to evaluate the use of prophylactic dressings (silicone foam, silicone tape and hydrocolloid) under N95/P2 respirators to determine which dressings, if any, could be applied and successfully pass a fit test.

METHODS

Design, population and setting

This prospective cross-sectional study used a convenience sample of HWs undergoing fit testing whilst wearing dressings under respirators from August and September 2021 during a spike in COVID-19 cases in one health service district in New South Wales (NSW), Australia. Gender and job role of all participating HWs was recorded. Ethical approval was obtained from the local health district hospital research ethics committee (No. X21-0298 & 2021/ETH11275).

The health service spans four hospitals and five community health centres in a high-density urban setting. The service provides care to a local population of approximately 700,000 people and employs approximately 14,000 staff. Playing a key role in the response to COVID-19, including redeploying staff to several COVID operations, the health service commenced a large-scale quantitative fit-testing (QNFT) program in April 2020 for HWs, students and contractors identified to be at risk of exposure to SARS-CoV-2 in the health service and beyond.

Outcome measures

The outcome measures for this study were the proportion of HWs fit-tested with prophylactic dressings achieving a successful fit (pass result), the association with specific prophylactic dressing and respirator type and HW's perception of comfort when dressings were applied.

Fit testing procedure

Fit testing was conducted by a trained fit tester as per the NSW Clinical Excellence Commission Respiratory Protection in Healthcare Manual using the Occupational Safety Health Standards³ modified fit test. The TSI PortaCount[®] Model was used to quantitatively calculate participant results for four activities: (1) bending over and returning to upright repeatedly for 50 seconds; (2) talking/reading aloud for 30 seconds; (3) head side-to-side for 30 seconds; and (4) head up-and-down for 30 seconds. The PortaCount[®] secure central database was held by director of the Centre for Education and Workforce, COVID-19 response team.

A fit check was initially performed followed by a fit test. Male participants enrolled were clean-shaven prior to the fit-test as part of NSW Clinical Excellence Commission Respiratory Protection in Healthcare Manual.³ Participants were fit-tested on one of five respirators in a sequential order: (1) flat fold BYD[™] N95; (2) 3M[™] 1860/1860 small; (3) duckbill type (BSN ProShield N-95); (4) Trident[®] P2; and (5) 3M[™] 1870 Aura. This order was determined by a fit-testing hierarchy based on respirator availability. To conserve respirator supplies, the first respirator to achieve a fit test pass was deemed appropriate for the HW. In the September 2021, the 1860 and 3M Aura were removed from the fit-testing hierarchy to preserve supplies.

Intervention

Once the respirator was deemed appropriate, the HW chose and applied a prophylactic dressing according to the practical tip sheet. Types of dressings were type 1: Mepilex[®] Border Lite with SofSicure silicone tape (Figure 1); type 2: Mepilex[®] Lite (Figure 2); and type 3: Comfeel[®] Plus Transparent (Figure 3). The fit test was then repeated.






Step 1	Step 2	Step 3
		
Perform Hand Hygiene. Apply skin barrier film/wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.	Use 1 single Mepilex® Lite dressing 4cm x 5cm for the bridge of the nose.	Peel backing. Apply Mepilex® Lite dressing 4cm x 5cm to the bridge of the nose.
Step 4	Step 5	Step 6
		
For the cheeks and under the eyes, use Sofsicure®.	Remove from packaging. With clean hands, tear off a piece of tap (approximately 6 to 8cm depending on facie size).	Apply Sofsicure® fixation tape to the cheeks under the eyes where the respirator/mask will be applied.

Figure 1: Type 1: Mepilex® border lite and sofsicure™







Step 1	Step 2	Step 3
		
Perform Hand Hygiene. As in previous tip sheet, apply 3M™ Cavilon™ wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.	Use 1 single Mepilex® Lite dressing 10cm x 10cm. The dressing will be cut in four (Step 3) . Place the unused pieces back in the plastic dressing packet, label the packet with your name and store the packet in a clean safe place for your subsequent applications OR use the remaining half to protect your ears – see Step 4 .	Fold the dressing in half and half again to cut 4 even strips. Tip: Cut the dressing perpendicular to the backing removal tabs so that all pieces are easy to apply.
Step 4	Step 5	Step 6
		
Option: Use one strip cut in half again for the back of your ears to protect your ears from eyewear and respirator/mask straps.	Apply the cut dressing section to the bridge of your nose.	Apply the respirator/mask and eye shield.

Figure 2: Type 2 Mepilex® Lite




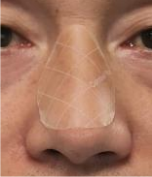


Step 1	Step 2	Step 3
		
<p>Perform Hand hygiene. As in previous tip sheet, apply 3M™ Cavilon™ wipe to the face where the dressing will be applied. Allow to dry before applying the dressing.</p>	<p>Use 1 single Comfeel transparent dressing 10cm x 10cm. The dressing will be cut into pieces. Place unused pieces in the plastic dressing packet, label the packet with your name and store the packet in a clean safe place for your subsequent applications.</p>	<p>Shape one quarter to fit your nose in terms of length and width (suggested shape in image above).</p>
Step 4	Step 5	Step 6
		
<p>Apply the cut dressing section to the bridge of your nose.</p>	<p>Apply the face mask and eye shield. Note: If you have a pressure injury, do not remove the Comfeel dressing at each PPE change. Keep it intact and wipe over it with an alcohol swab. Remove when dressing starts to peel off or after 3 to 7 days.</p>	<p>Use Adhesive Remover when removing Comfeel to avoid stripping of your skin.</p>

Figure 3: Type 3 Comfeel® Plus Transparent

Type 1 and 2 dressings were used as a skin injury preventative measure because of the dressing properties. Safetac® has been clinically proven to prevent skin trauma upon removal of dressings as well as preventing maceration and pain.¹⁴ Type 3 dressings were used on HWs who had already developed a skin injury. Trauma to the skin can occur if dressings are removed frequently, as would occur when putting on and removing PPE; and the type 3 dressing¹⁵ is intended to stay intact on the skin for several days. In this instance HWs were advised to wipe over the outside of the dressing with alcohol when removing PPE.

Health workers' perception of comfort

Once the repeat fit test was performed, HWs were asked to rate their comfort level on a four-point Likert scale: markedly comfortable=4, moderately comfortable=3, marginally comfortable=2; no different=1.

Data collection

A data collection tool was developed in REDCap version 11.0.3 software (a proprietary electronic system for building and managing online surveys and data)¹⁶ by the lead author, in consultation with the co-authors. The tool captured HWs' gender and role, type of fit respirator deemed appropriate (achieved pass fit \geq 100), results of fit test factor of the respirator, prophylactic dressing type, results of fit test factor of the respirator with a prophylactic dressing, any comments from the HWs and comfort of the respirator with the dressing. Access to TSI PortaCount[®] was negotiated with the health service COVID-19 response team. Participants were anonymised and randomly assigned an enrolment number.

Data analysis

The sample was summarised descriptively. The proportion of pass marks in the fit test was determined by dressing and respirator type. Associations between dressing type and outcome; respirator type and outcome; and perceived comfort and dressing type were tested using uncorrected chi-squared tests for association. Subsidiary analyses were conducted to determine whether initial fit test scores differed across specific respirator–dressing combinations and whether post-fit test scores differed across specific respirator–dressing combinations achieving a pass grade. A total pass level fit factor of \geq 100 was required (with the highest possible score of 200).

The effect of respirator type as a confounding variable was assessed by comparing the unadjusted odds ratio (OR) of a pass in different dressing types with the corresponding pooled OR stratified over respirator type.

RESULTS

Descriptive summary of data

Data were obtained from 600 participants. About three quarters of participants were female, and just under half were nurses (Table 1).

Table 1: participant demographics

Variable	Frequency (%)
Gender	
Female	434 (72.3%)
Male	166 (27.7%)
Role	
Administration	23 (3.8%)
Allied Health practitioner	70 (11.7%)
Cleaner	29 (4.8%)
Doctor	65 (10.8%)
Manager	28 (4.7%)
Nurse	258 (43.0%)
Porter	11 (1.8%)
Student	46 (7.7%)
Technical/research	20 (3.3%)
Other	50 (8.3%)

Participants fit-tested one of five respirator types and one of the three dressing types worn with their respirators. One participant did not have valid data and was removed from the analysis. Four participants each selected two dressing types, both of which were analysed. Hence 603 dressing-respirator combinations were obtained (Table 2). Different sizes of the same make/model of respirator were not differentiated. Dressing type 3 was selected by only 2 participants and was removed from further analysis.

Table 2: Respirator/dressing selections

Respirator	Dressing			Total
	Type 1	Type 2	Type 3	
3M 1860 Small/Universal	104	7	0	111 (18.4%)
3M 1870+ Aura	40	22	0	62 (10.3%)
BSN Orange Duckbill Medium/Small	67	63	0	130 (21.6%)
BYD N95 Respirator	54	53	1	108 (17.9%)
Trident	79	112	1	192 (31.9%)
Total	344 (57.0%)	257 (42.6%)	2 (0.3%)	603 (100%)

Initial fit tests

All respirators achieved satisfactory initial fit scores, ranging from 167.9 points (BYD) to 192.7 points (Trident) out of a possible 200 points; with negligible difference between scores obtained with dressing types 1 and 2 (Table 3).

Comparing performance by dressing and respirator type

Over the complete cohort selecting dressing types 1 or 2, 382 participants achieved a pass (63.6%). A successful fit was achieved by 202 of 344 participants (58.7%) for dressing Type

1, and 180 of 257 participants (70.0%) for dressing Type 2. An uncorrected chi-squared test for association (at 5% significance level) revealed a significant association of moderate magnitude between dressing type and outcome ($\chi^2_{(1)}=8.14$; $p=0.004$; $\phi=0.116$). A pass mark was achieved by 81 of 111 participants (73%) for the 3M™ 1860 respirator; 41 of 62 (66.1%) for the 3M™ 1870+ Aura respirator; 65 of 130 participants (50%) for the BSN orange duckbill respirator; 32 of 108 participants (29.6%) for the BYD™ respirator and 165 of 192 participants (85.9%) for the Trident® respirator. (Table 3). An uncorrected chi-squared test for association (at 5% significance level) revealed a significant association of high magnitude between respirator type and outcome ($\chi^2_{(4)}=110.1$; $p<0.001$; $\phi=0.427$). Chi-squared testing suggests that respirator type is a stronger predictor of success than dressing type.

The best-performing respirator-dressing combination was the Trident® respirator in conjunction with dressing Type 2 (90.2% pass rate). Other combinations showing high pass rates were the Trident® respirator in conjunction with dressing Type 1 (79.1%); the 3M™ 1860 respirator in conjunction with dressing Type 1 (74%); and the BSN orange duckbill respirator in conjunction with dressing Type 2 (69.8%). The poorest-performing combination of respirator and dressing was the BYD™ respirator in conjunction with dressing Type 1 (25.9% pass rate).

Some evidence for effect modification existed: the proportion of pass grades across dressing types was approximately similar when the 3M™ 1870+ Aura and BYD™ respirators were used, but different when other respirators were used, particularly the BSN orange duckbill respirator.

Analysis conducted to determine whether the post-fit test scores differed across specific respirator-dressing combinations achieving a pass grade revealed little evidence for effect modification with respect to post-fit scores in cases achieving a pass grade, with similar post-fit scores for each respirator type with either dressing type (Table 3).

Odds of a pass mark were 1.42 and 2.34 for dressing Types 1 and 2, respectively; the corresponding unadjusted OR for a pass mark using Type 2 rather than Type 1 dressing was 1.64 (95% CI 1.1 to 2.32). The corresponding Mantel–Haenszel OR analysed over strata defined by respirator type was 2.02 (95% CI 1.35 to 3.02).

Table 3: Initial and post-fit scores and pass rates by dressing and respirator type (dressing types 1 and 2 only)

Respirator type	Initial fit scores (mean (SD))	Post-fit test scores (mean (SD)); pass rates frequency (valid %)		
		Dressing type 1	Dressing type 2	Total
3M 1860 Small/Universal	181.1 (28.1)	171.3 (30.9) 77 (74.0%)	198.8 (1.50) 4 (5.71%)	172.6 (30.7) 81 (73.0%)
3M 1870+ Aura	181.9 (28.5)	183.6 (28.7) 27 (67.5%)	154.4 (34.2) 14 (63.6%)	173.6 (33.4) 54 (66.1%)
BSN Orange Duckbill Medium/Small	180.1 (28.8)	174.8 (27.6) 21 (3.1.3%)	179.1 (28.5) 44 (69.8%)	177.7 (28.1) 65 (50.0%)
BYD	167.9 (34.6)	139.4 (28.3) 14 (25.9%)	150.4 (29.8) 17 (32.1%)	145.5 (29.1) 31 (29.0%)
Trident	192.7 (20.8)	183.2 (28.7) 63 (79.7%)	192.5 (18.1) 101 (90.2%)	189.0 (23.4) 164 (85.9%)
Total	182.3 (28.8)	174.8 (31.2) 202 (58.7%)	182.4 (28.0) 180 (70.0%)	178.4 (29.9) 382 (63.6%)

Comfort perception

Most respondents reported the degree of comfort as ‘markedly comfortable’, the most positive of all available options, with all other options combined (‘moderately comfortable’, ‘marginally comfortable’ and ‘no difference’) amounting to less than 20% of all responses. Hence there were no substantive differences in responses by either dressing type or respirator type, with uncorrected chi-squared tests for association revealing no evidence for associations between perceived comfort and either dressing type ($\chi^2_{(3)}=4.56; p=0.207$) or respirator type ($\chi^2_{(3)}=2.04; p=0.565$).

DISCUSSION

To our knowledge, this is the first large-scale study evaluating fit test outcomes of prophylactic dressings worn under respirators to prevent skin injury. A high proportion (63.6%) prophylactic dressings used under respirators, achieved a fit test pass. There were slight differences in the initial fit test scores across respirator types without dressings. Pass grades were significantly ($p<0.001$) and substantively higher for Trident® respirators than for 3M™ or BSN respirators, and substantively higher than for BYD™ respirators; hence respirator type is a strong predictor of success.

Initial fit scores were similar across the Type 1 and Type 2 dressing. However, the best-performing combinations of respirators and dressings were Trident® respirators and dressing Type 2 (90.2% pass rate), and Trident® respirators and dressing Type 1 (79.7% pass rate). Fit-testing with Trident® respirators, following the application of dressing Type 2 demonstrated higher respirator fit score (192.5 points (SD 18.8 points)) and comfort level (80 of 97 respondents (82.5%) gave the maximum possible comfort rating) than any other

dressing-respirator combination. This suggests that Type 2 dressing not only redistributes pressure and protects the skin from injury but improves the respirator seal when combined with the Trident® respirator. Improved fit factor results were also reported in a pilot cross-over study conducted in New Jersey¹⁷ on the impact of various skin barriers under respirators on fit test outcomes. Although this study had a small sample and used different dressings, it reported that 3M™ Cavilon™ No Sting barrier film under respirators provided a significant increase in the respirator seal, ensuring protection and better fit.

The poorest-performing respirator-dressing combinations were BYD™ respirator, dressing Type 1 (25.9% pass rate); BYD™ respirator, dressing Type 2 (32.1% pass rate); and BSN orange duckbill respirator, dressing Type 1 (31.3% pass rate). However, Ng et al.¹² reported higher pass rates with BYD™ respirators and BSN ProShield (85%; 81%) when a hydrocolloid was applied, compared with our study pass rates when silicone foam dressings were applied (Type 1, 26%; Type 2, 30%). In fact, Ng et al.'s¹² pass rates for all respirators used in our study was higher than ours when a hydrocolloid was applied (81% v. 63.7%). We could not compare our data from the two participants in our study who were fit-tested with a hydrocolloid and who were removed from the analysis because of low numbers.

There is evidence for moderate levels of effect modification: performance of each dressing type varied over strata defined by respirator type. This is particularly marked for the BSN orange duckbill respirator (31.3% and 69.8% pass rates under dressing Types 1 and 2 respectively). Smaller effects were observed in other respirators. Odds of a pass grade, adjusting for respirator type, were 102% higher for dressing Type 2 than Type 1. The difference between this statistic and the earlier corresponding unadjusted statistic reflects effect modification in the analysis of specific respirator–dressing combinations.

Although a higher fit test pass was achieved with hydrocolloids by Ng et al.,¹² our study trialled soft silicone Mepilex[®] Border Lite and Mepilex[®] Lite, as per our health service protocol for preventative measures because of its Safetac[®] technology. The Safetac[®] technology reduces friction and pressure and does not cause skin trauma when frequently removed and applied to the face when compared with a hydrocolloid dressing.^{11,18} Unsurprisingly, most participants reported greater comfort with dressings under the respirators. Most participants responded ‘markedly comfortable’ across all respirators and both dressing types. Mepilex[®] Border Lite and Mepilex[®] Lite are renowned for their comfort and pressure reduction.^{14,18,19} Cohen et al. studied pressure on facial tissues when using non-invasive ventilation respirators and reported reduced facial tissue stresses and deformations when Mepilex[®] Lite was applied under the respirator. Areas where pressure was markedly reduced were the bridge of the nose and cheeks, the same as HWs in this study. This is consistent with a Turkish small observational study on Mepilex[®] Lite under PPE (respirators, goggles), which reported a significant reduction in facial skin injuries in HWs in controls (N=20) compared with the intervention group (N=1).²⁰

The results of this study have guided developments in policy and practice at both health service and state-wide level. At our health service, a policy for the use of dressings under respirators has been implemented. HWs have been informed to repeat an annual fit test with both the respirator and the dressing to ensure that the selected respirator is well fitted in both scenarios.²¹ The policy contains information on selected dressings under respirators, safe application of dressings under respirators and respirator fit check and test with a dressing. At state-wide level, the Respiratory Protection Program in Healthcare³ has been updated to a manual to reflect the outcomes of this study.²²

Limitations in our study included not being able to blind fit testers to dressings or dressing types. Even with 603 included cases, the number of respirator/dressing combinations led to low frequencies of some combinations. This reduced the precision of estimates obtained from such groups. Other respirators and dressings are available which were not tested in the router.

Conclusion

Skin injuries in HWs wearing PPE, particularly under respirators for prolonged periods, have been reported worldwide. Protective dressings worn under respirators have the potential to compromise respirator seal, thereby achieving a failed fit test outcome. Our study demonstrated that prophylactic dressings worn under some respirators can achieve a successful fit test in a relatively high number of cases. Trident® respirators had the highest probability of successful fit, while BYD™ respirators have the lowest probability. A combination of the Trident® respirator and Mepilex® Lite dressing yields optimal results. Respirator type is a stronger predictor of success than dressing type. Comfort testing revealed no substantive differences across respirators or dressings.

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