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**Impact on quantitative fit test results after application of prophylactic hydrocolloid dressing under N95 respirators**

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Abstract

Objective
Discomfort and device-related pressure injury (DRPI) caused by N95 filtering facepiece respirators (FFRs) are common. The use of prophylactic hydrocolloid dressings is one of the strategies that may improve comfort and reduce DRPI. In this study, we investigated the impact of these dressings on N95 respirator fit.

Methods
We performed a repeat quantitative fit testing through the Respiratory Protection Program on 134 healthcare workers (HCWs), who applied hydrocolloid dressings on the bridge of their nose under the N95 FFRs that they passed the initial fit test but reported discomfort with.

Results
We found that the fit test pass rates, with the hydrocolloid dressings in place, for the semi-rigid cup style (3M™ 1860), the vertical flat-fold style (BYD), the duckbill style (BSN medical ProShield® and Halyard Fluidshield*), and the three-panel flat-fold style (3M™ Aura) N95 FFRs were 94% (108/115), 85% (44/52), 81% (87/108) and 100% (3/3) respectively. There was a statistically significant reduction in the overall fit factors for both the vertical flat-fold and duckbill type N95 respirators, after the application of hydrocolloid dressings.

Conclusions
Hydrocolloid dressings are likely to disturb the mask seal for non-rigid style N95 FFRs, in particular, the vertical flat-fold style and the duckbill style N95 FFRs. Given the risk of mask seal disturbance of N95 respirators as shown in this study, we advocate that any HCW requiring the use of prophylactic dressings should undergo repeat quantitative fit testing with the dressing in place prior to using the dressing and mask in combination.
Introduction

During the COVID-19 pandemic, in order to minimize the risk of airborne infection transmission, many frontline healthcare workers (HCWs) are required to wear N95 filtering facepiece respirators (FFRs) for long periods of time. Some HCWs would extend the use of their N95 FFRs, especially during the early phase of the pandemic, in order to preserve personal protective equipment, as per the National Institute for Occupational Safety and Health guideline. As a result, there have been many reports of skin damage, in particular, device-related pressure injuries (DRPI) over the face, especially over the nasal bridge. A pressure injury is localised skin injury usually over a bony prominence caused by extended pressure or shear. A cornerstone of pressure injury prevention and management is removal of the pressure.

Since pressure cannot be readily removed in this circumstance, many mitigating strategies have been recommended by different organisations to prevent skin injury under N95 FFR. One of the strategies includes the use of prophylactic dressing over the nasal bridge to prevent pressure injury. However, there is concern about the integrity of the N95 mask seal over the skin dressing on the face. There is currently very limited data on the impact of skin dressing on N95 respirator fit. A few small studies, which used qualitative fit testing to assess the respirator fit, showed conflicting results.

Our local government, the Victorian Department of Health and Human Services (DHHS) in Australia, recommends the use of thin hydrocolloid dressing (e.g. DuoDerm) or foam dressing (e.g. Mepilex lite) to prevent facial injury from extended N95 respirator use. However, it cautions the uncertainty as to whether this practice will increase the risk of
COVID-19 infection. One study by Guschel et al.\textsuperscript{12} demonstrated an effective seal (fit factor over 100) of N95 respirators over hydrocolloid dressings from a quantitative fit test, which is more objective than a qualitative fit test. However, there were only two participants in the study.

In this study, we wanted to gather more information, through the Respiratory Protection Program (RPP) at our institution, on whether the use of thin hydrocolloid dressing over the nasal bridge will compromise the N95 respirator fit and seal. A hydrocolloid dressing was chosen to test as it was already being used by some staff throughout the hospital. We compared the overall pass rates and also the overall fit factors on four different types of N95 FFRs before and after the application of hydrocolloid dressing on each participant.

Methods

This study was conducted through the RPP, which was implemented at the Royal Melbourne Hospital in October 2020, as an initiation by the Victorian Government\textsuperscript{13}. The project was approved by the local ethics committee, Melbourne Health Human Research Ethics Committee (QA 2020174).

As part of the RPP requirement, our HCWs completed a basic demographic survey, received an online education package and also participated in mandatory quantitative fit testing on at least three out of four types of N95 FFRs, as per DHHS guideline\textsuperscript{13}. The order of the N95 FFRs being tested was: (1) Semi-rigid cup type respirator: 3M\textsuperscript{TM} 1860 or 1860S (3M\textsuperscript{TM}, St. Paul, MN, USA); (2) Flat-fold cup type: BYD N95 respirator (BYD Care, Los Angeles, CA, USA); (3) Duckbill type: BSN medical ProShield\textsuperscript{®} N-95 masks (BSN medical, Mount...
Waverley, Victoria) or Halyard Fluidshield® N95 masks (Halyard, Alpharetta, Georgia, USA); and (4) Three-panel flat-fold type: 3M™ Aura™ 9320A+ (3M™, St. Paul, MN, USA). These four types of N95 FFRs were selected because they were readily available and used at our institution at the time of the study, and they also encompassed a wide range in their shape design. The goal was to ensure that each HCW could achieve a successful respirator fit with at least two types of N95 FFRs if possible.

The quantitative fit testing was performed by fit testers, who were all qualified by a certified training program, using a Portacount machine (PortaCount® Pro+ 8038, TSI Incorporated, St Paul, Minnesota, USA). The test was carried out according to the United States Occupational Safety and Health Administration’s modified ambient aerosol condensation nuclei counter quantitative fit testing protocol for filtering facepiece respirators, consisting of four exercises: 1) Bending over at the hips and returning to upright repeatedly while taking two breaths during the bend over for 50 seconds; 2) Reading a standardized text aloud for 30 seconds; 3) Moving the head from side to side for 30 seconds; and 4) Moving the head up and down for 30 seconds. All the participants were free of facial hair and performed a user seal check before the fit test. The test was observed throughout by a trained operator, who provided consistent and constructive feedback to the individual. Any breach of the protocol was addressed by recommencing the test immediately. Participants were allowed to adjust the position of the mask and repeat the user seal check if necessary. Participants were invited to report any discomfort or other issues with the masks they were testing.
The fit factor was calculated by the Portacount machine for each exercise by dividing the concentration of the particles in ambient air outside the mask by that inside the mask. An overall fit factor is calculated by the following equation:

$$\text{Overall FF} = \frac{1}{\frac{1}{FF_1} + \frac{1}{FF_2} + \frac{1}{FF_3} + \cdots + \frac{1}{FF_n}}$$

where $FF_n$ = fit factor for each exercise and $n$ = number of exercises.

Overall fit factor of >100 was considered a pass.

As per our RPP protocol, at the end of the quantitative fit testing, the participants were given a result sheet, which listed which N95 FFRs were tested and whether it was a pass or fail for each respirator. They were then immediately invited to repeat the quantitative fit testing of the N95 FFRs that they passed but reported discomfort when wearing. They were re-tested with a thin hydrocolloid dressing (DuoDerm Extra Thin Hydrocolloid Dressing, Australian Home Nursing Supplies, Chelsea, VIC, Australia) applied on their nasal bridge under the respirator.

The hydrocolloid dressing was cut into a rectangular piece with a dimension of about 3cm x 15cm, as per the Victorian DHHS guideline. The participant would place it on the bridge of the nose across each cheekbone. The dressing was placed under the edges of the N95 respirator. The participant would check in front of a mirror to ensure the dressing was wrinkle free. They would then perform a user seal check before repeating the quantitative fit test with a qualified fit tester, as discussed above.

The primary outcome was to investigate the overall pass rate of each type of the N95 FFR after applying the hydrocolloid dressing. The secondary outcome was to compare the overall fit factors for each type of the N95 FFR before and after the application of the dressing.
Statistical Analysis

This study was conducted from the start of October until the end of December 2020. We included all the data from HCWs who participated in the repeat quantitative fit testing with the hydrocolloid dressing. Basic demographic information was collected from the RPP survey via REDCap 10.5.2 (Vanderbilt University, Nashville, Tennessee, USA). The quantitative fit test results were recorded using a standard spreadsheet (Excel; Microsoft, Redmond, WA, USA). Descriptive statistics were used to present the demographic data, quantitative fit factors and pass rates. Wilcoxon sign rank test was used to compare the overall fit factor of N95 FFR with and without hydrocolloid dressing on. A p-value of <0.05 was considered statistically significant.

Results

A total of 214 HCWs participated in the RPP during the study period. Out of these HCWs, 134 repeated the quantitative fit testing with the application of hydrocolloid dressings under the N95 FFRs that they passed initially. Table 1 shows the participants’ demographic data. Most of the participants were female nursing staff with normal BMI.

Table 2 shows the quantitative fit test results. One hundred and fifteen participants passed the quantitative fit test with the semi-rigid cup type respirator (3M 1860 or 1860S) respirators initially, but only 108 of them passed when they repeated the same test with the hydrocolloid dressing on, giving the overall pass rate of 94%. There was no significant change in the overall fit factor.
There was a statistically significant reduction in the overall fit factor for both the flat-fold cup type N95 respirator (BYD) and the duckbill type (BSN medical ProShield or Halyard Fluidshield) N95 respirators, after the application of hydrocolloid dressing. The fit test pass rate with the prophylactic dressing was 85% and 81% respectively (Table 2). The significant drop of the fit factors occurred during fit test exercise one, two and four, which were bending over the hips, speaking out-loud; and flexing and extending the neck.

Only three participants repeated the quantitative fit test with the three-panel flat-fold type respirator (3M Aura) and all of them achieved an overall fit factor >100 with the hydrocolloid dressing on.

Discussion

Discomfort and pressure injury caused by N95 masks was and remains a significant issue for HCWs during the COVID-19 pandemic, impacting on the ability of staff to provide care whilst remaining safe from infection \(^2\,^5\). There is evidence in the literature that prophylactic hydrocolloid dressings improve comfort and reduce DRPI \(^16\,\!17\). However, there is little evidence as to the impact of these dressings on mask performance.

Our study demonstrated a high fit test pass rate for the semi-rigid cup style respirator (3M 1860 or 1860S) when it was worn with a hydrocolloid dressing over the nasal bridge. This is reassuring data, as many of our staff members find this cup style mask uncomfortable. This finding is also useful for HCWs who are required to use this type of respirator due to supply issues or poor fit with other types of N95 respirators.
In contrast, there was a statistically significant decrease in the fit test pass rates for the non-rigid style N95 respirators, i.e. the vertical flat-fold cup type and the duckbill type. For the duckbill type N95 respirator, this is likely attributable to the different physical characteristics of the mask that make it more susceptible to vertical shearing forces and therefore more likely to slide vertically over the hydrocolloid dressing, thereby disturbing the fit. A similar phenomenon would be observed with the vertical flat-fold type masks which have a limited tolerance for vertical shearing forces.

Our results would suggest that all staff should have a formal quantitative fit test with hydrocolloid dressing in place if they are planning to use a hydrocolloid dressing for skin protection from vertical flat-fold or duckbill type N95 respirators. Respiratory protection programs should consider mandating repeat fit testing of all types of N95 respirators when it is planned to be used with a hydrocolloid dressing, as a small number of subjects did fail fit testing to even the semi-rigid cup when a hydrocolloid dressing was introduced.

Our study design had several limitations. First of all, the sample size was small, especially for the BYD and the 3M Aura N95 respirators. The initial fit test pass rate for the BYD N95 respirators was low among our staff, therefore not many participants could repeat the test with the hydrocolloid dressing put on. Most of our staff found the 3M Aura N95 respirators were comfortable enough that they did not require prophylactic dressing. Second, there was no blinding in this study. We could not blind the fit testers due to the obvious presence of the dressing.

Additional factors to consider are whether the dressing represents a doffing risk, with the potential for contamination during doffing, although a small study showed no skin
contamination from removal of the dressing. Hydrocolloid dressings are designed to stay in-situ for several days. Removal of hydrocolloids has been shown to cause skin stripping. The combination of removing the hydrocolloid earlier than designed for and the repeated application and removal (i.e. at the end of each shift over several days) therefore has the potential to negatively impair the skin barrier function. This increases the likelihood of HCWs developing skin injuries, such as contact dermatitis. The risks versus benefits of the dressing must be carefully considered.

It is important to emphasise that discomfort and DRPIs due to N95 FFRs can cause physical and emotional stress to HCWs. Prophylactic hydrocolloid dressings represent a potentially effective strategy to relieve this problem. Our study has demonstrated that hydrocolloid dressings are more likely to disturb the mask seal for non-rigid style N95 FFRs, in particular, the vertical flat-fold (BYD) and the duckbill type (BSN medical ProShield and Halyard Fluidshield), rather than the semi-rigid cup style (3M 1860) N95 FFRs. However, there is the potential for the dressing to disturb the seal of any type of N95 respirators, and we therefore advocate that any HCW requiring use of prophylactic dressings should undergo repeat quantitative fit testing with the dressing in place prior to using the dressing and mask in combination.

Acknowledgement

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There was no external funding provided for this study.

Conflict of interest:

There are no competing interests or conflict of interest declared.
References


Table 1. Participants’ demographic characteristics. Values are presented as number (percentage), mean(standard deviation) or median(IQR[range]).

<table>
<thead>
<tr>
<th></th>
<th>n=134</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, yrs</td>
<td>37 (10)</td>
</tr>
<tr>
<td>Sex (F:M:Other)</td>
<td>101:31:2</td>
</tr>
<tr>
<td>BMI, kgm$^2$</td>
<td>25.2(4.4)</td>
</tr>
<tr>
<td>Race (Caucasian:Asian:Other)</td>
<td>85:46:3</td>
</tr>
<tr>
<td>Profession</td>
<td></td>
</tr>
<tr>
<td>Nursing</td>
<td>97 (72%)</td>
</tr>
<tr>
<td>Medical</td>
<td>21 (16%)</td>
</tr>
<tr>
<td>Allied health</td>
<td>4 (3%)</td>
</tr>
<tr>
<td>Other</td>
<td>12 (9%)</td>
</tr>
<tr>
<td>Year of working experience</td>
<td>10[5-16[1-40])</td>
</tr>
</tbody>
</table>
Table 2. Overall fit test pass rate and fit factor with and without hydrocolloid dressing for the four different types of N95 filtering facepiece respirators. Values are expressed as number (percentage), median[IQR(range)].

<table>
<thead>
<tr>
<th>Type</th>
<th>Passing rate with hydrocolloid dressing</th>
<th>Overall fit factor without hydrocolloid dressing</th>
<th>Overall fit factor with hydrocolloid dressing</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Semi-rigid cup type¹</td>
<td>108/115 (94%)</td>
<td>196[152-201][105-201]</td>
<td>201[163-201][52-201]</td>
<td>0.40</td>
</tr>
<tr>
<td>Flat-fold cup type²</td>
<td>44/52 (85%)</td>
<td>191[168-201][109-201]</td>
<td>169[122-197][20-201]</td>
<td>0.00*</td>
</tr>
<tr>
<td>Duckbill type³</td>
<td>87/108 (81%)</td>
<td>199[159-201][100-201]</td>
<td>188[115-201][20-201]</td>
<td>0.00*</td>
</tr>
<tr>
<td>Three-panel flat-fold type⁴</td>
<td>3/3 (100%)</td>
<td>196[161-201][161-200]</td>
<td>201[149-201][149-201]</td>
<td>0.78</td>
</tr>
</tbody>
</table>

* Statistically significant.

1. Semi-rigid cup type respirator: 3M™ 1860 or 1860S; 2. Flat-fold cup type: BYD N95 respirator; 3. Duckbill type: BSN medical ProShield® N-95 masks or Halyard Fluidshield* N95 masks; 4. Three-panel flat-fold type: 3M™ Aura™ 9320A+.