

# Fit Factor Change on Quantitative Fit Testing of Duckbill N95 Respirators with the Use of Safety Goggles

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## ABSTRACT

N95 respirators and safety goggles are important components of personal protective equipment to reduce the spread of airborne infections, such as COVID-19, among healthcare workers. Poor N95 respirator seal may reduce its protective effect, thereby increasing transmission. Quantitative fit testing is an established way of assessing the N95 respirator fit, which provides a quantitative measure for seal, called the fit factor. Duckbill N95 respirators frequently fail the fit test. We hypothesized that using safety goggles with a wraparound elastic headband will increase their fit-factor by reinforcing the seal between the face and the upper margin of the respirator. We studied the effect of safety goggles with a wraparound elastic headband (3M™ Chemical Splash Resistant Goggles, ID 70006982741) on the fit factor of two types of Duckbill N95 respirators (Halyard FLUIDSHIELD\*3, Model 99SA070M, and ProShield® N95 Model TN01-11) in 63 healthy volunteers in a nonrandomized, before-and-after intervention study design. The mean fit factor increased from 69.4 to 169.1 increased from 17/63 (27%) to 46/63 (73%) after the intervention ( $p < 0.0001$ , OR 3 [95% CI = 4.9–1223]). This is the first study to explore the impact of safety goggles on N95 respirator fit. We conclude that the use of safety goggles with a wraparound elastic headband increases the fit factor of the tested Duckbill N95 respirators.

**Keywords:** Eyeglasses, HCW (Healthcare workers), Infectious diseases, Intensive care, N95 MASK, N95 respirators, Occupational injury, Personal protective equipment, Safety.

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## INTRODUCTION

N95 respirators are an essential component of personal protective equipment (PPE) for healthcare workers (HCW) looking after patients with infections with a droplet or airborne transmission, like COVID-19. However, the N95 respirator can protect the user only if there is an adequate seal between the respirator and the user's face.

During the COVID pandemic, the availability of the N95 respirators has been overwhelmed by demand, particularly in developing countries.<sup>1,2</sup> Poorly fitting N95 respirators offer little or no protection to the HCW exposing themselves to potentially high inoculum of infectious viruses while performing high-risk procedures like endotracheal intubation.<sup>3</sup> Indeed, HCW have been disproportionately affected by acquiring infection in their line of work.<sup>4,5</sup> The importance of a good seal between the face and the N95 respirator in preventing the transmission of infection to the HCW cannot be emphasized enough.

The "user seal check" is recommended by most N95 respirator manufacturers to self-determine a leak.<sup>6</sup> The user seal check is done by inhaling and exhaling sharply and observing for air leaks around the nose and respirator edges. The user seal check, however, has poor sensitivity in detecting leaks around the respirator and there is no other widely available point-of-care test for determining the adequate fit of the N95 respirator.<sup>6,7</sup>

Fit testing, e.g., using a quantitative fit test (QnFT), is recommended to determine the best-fitting respirator.<sup>6,8,9</sup> In developing countries, however, QnFT is not commonly performed.

Duckbill N95 respirators are commonly used worldwide but may be associated with a high failure rate during QnFT.<sup>10</sup> A typical site for the leak is between the nasal and maxillary region, as illustrated in Figure 1B.<sup>11,12</sup>

Eye protection (for example, goggles or a face shield) is a mandatory component for airborne precautions in PPE.<sup>13–15</sup>

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Safety goggles with a wraparound elastic headband, as shown in Figures 1B and 2 are widely available. The lower margin of the safety goggles presses the upper margin of the respirator against the face, which may improve the seal.

Our study aims to test the hypothesis that the fit factor (FF) of Duckbill N95 respirators, as measured by quantitative fit testing, may be improved using safety goggles with a wraparound elastic headband.

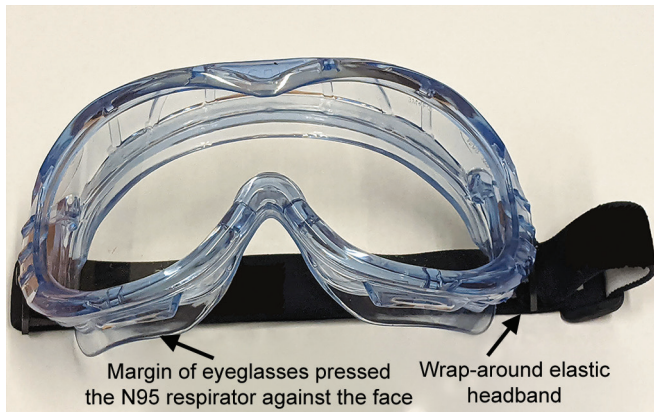
## MATERIALS AND METHODS

### Participants

All HCW were eligible to participate in the study. Men with beard and HCW with hypersensitivity to isopropyl alcohol or nebulized

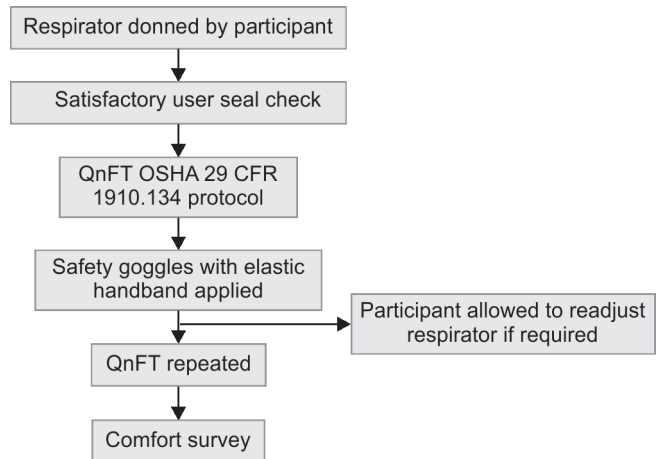


**Figs 1A and B:** (A) Common site for leaks for N95 respirators; (B) Safety goggles with headband presses the respirator against the skin to seal the gap that results in a leak. The sampling port in the respirator used for QnFT with PortaCount is also shown



**Fig. 2:** 3M™ chemical splash-resistant goggles (3M™ ID 70006982741 Australian standard AS/NZS 1337)

**Flowchart 1: Study pathway**



saline were excluded. Male participants were required to have shaved on the day of testing. The participants were a convenience sample consisting primarily of nurses and medical officers working at the Prince of Wales Hospital in Sydney. The data were collected between October and December 2020.

**Study Design**

We used a before-and-after study design. QnFT was done before and after the application of safety goggles. The study method is outlined in [Flowchart 1](#). Once both QnFT were complete, the participants completed a survey about the physical discomfort with the N95 respirators and the addition of safety goggles.

**Choice of Respirators**

Participants were tested with one of two Duckbill N95 respirators, which are in common use in the healthcare setting: Halyard FLUIDSHIELD\* 3 N95 Duckbill respirator (model number 99SA070M, CDC approval number 84A-3348) or the ProShield® N95 Duckbill respirator (BSN Medical Australia, model number TN01-11, CDC approval number 84A-3348).<sup>16</sup> The allocation of masks was not randomized. Participants were given the respirators based on the availability in the area in the hospital where they worked.

**Choice of Safety Goggles**

In this study, 3M™ Chemical Splash-Resistant Goggles (3M™ ID 70006982741 Australian standard AS/NZS 1337), as shown in [Figure 2](#), were used. These safety goggles have a soft circumferential lip around the eyeglasses, pressing the N95 respirator against the face. There is a wide elastic wraparound headband, which keeps the safety goggles pressed against the respirator and face.

**Quantitative Fit Test Equipment**

The QnFT was done using PortaCount Respirator Fit Tester 8048 (TSI Incorporated, Shoreview, Minnesota, USA 55126), as shown in [Figure 3](#). It uses a continuous flow condensation nuclei counter technology to count the number of particles detected outside and inside the respirator. The air is pumped across a filter saturated with isopropyl alcohol. As the aerosolized particles pass through, they increase in size due to the condensation of isopropyl alcohol on the surface. The particles scatter light when it passes through a focused beam of laser. The number of particles is determined by a photodiode by counting the flashes of scattered light. The particles may be any aerosol in ambient air, larger than approximately 0.015 microns. The respirator is probed using a special metallic tube to sample the air inside the respirator, as shown in [Figure 1B](#),





**Fig. 3:** PortaCount Respiratory Fit Tester 8048 condensation nuclei counter unit. Published with permission from airmet.com.au (Air-Met Scientific Pty Ltd. Nunawading, Victoria 3131, Australia)

**Box 1:** OSHA 29 CFR 1910.134 Quantitative fit-test protocol

1. ff1: normal breathing 60 seconds
2. ff2: deep breathing 60 seconds
3. ff3: move head from side to side 60 seconds
4. ff4: move head up and down 60 seconds
5. ff5: read the “rainbow passage” 60 seconds
6. ff6: bend forward 60 seconds
7. ff7: normal breathing 60 seconds

panel B. Since the microscopic particles in the air cannot pass through the material of the N95 respirators, it is assumed that the particles measured inside the respirator must have reached there due to the leak.<sup>17</sup> If the ambient air particle count was below the threshold for N95 respirator fit testing, TSI Model 8026 particle generator was used. The OSHA 29 CFR 1910.134 QnFT protocol was used for testing.<sup>18</sup> According to the protocol, the participants performed a series of activities for 60 seconds each, as outlined in Box 1. Dividing the number of particles measured outside the respirator by the number of particles measured inside the respirator yielded the FF for each activity. Once all the activities were complete, overall FF was calculated for the respirator using the equation as shown in Equation 1.<sup>19</sup> Higher FF indicates a low concentration of particles inside the respirator and, therefore, a better seal. An overall FF  $\geq 100$  is considered an adequate seal for the N95 respirators.<sup>20</sup>

FF  $\geq 100$  was categorized as “pass” and FF  $< 100$  was categorized as “fail.” If FF was more than 200, the PortaCount assigned an FF of  $> 200$ , i.e., and higher values were truncated.

$$\text{Overall FF} = \frac{7}{\frac{1}{ff1} + \frac{1}{ff2} + \frac{1}{ff3} + \frac{1}{ff4} + \frac{1}{ff5} + \frac{1}{ff6} + \frac{1}{ff7}}$$

**Eq. 1:** Overall fit factor (FF) calculation using Quantitative Fit Test. ff1—fit factor normal breathing, ff2—deep breathing, ff3—head side to side, ff4—head up and down, ff5—reading aloud, ff6—bending over, and ff7—normal breathing again

**Table 1:** Characteristics of the participants

Parameters	Results
Number of participants	63
Number of male (%)	26 (41%)
Median age in years (IQR)	31.0 (9.2)
BMI (SD)	24.7 (3.8)
Number of participants with BMI $> 30$	8 (13%)

IQR, interquartile range; BMI, body mass index; PPE, personal protective equipment

**Quantitative Fit Test Procedure**

For this study, the N95 respirator was prepared for QnFT by inserting an adapter for the PortaCount sampling port as shown in Figure 1B. The study participants donned the respirator and then performed a USC as per the manufacturers’ recommendation. The PortaCount adapter was occluded while the participant did the user seal check. The PortaCount sampling port was then attached to the N95 respirator, and the QnFT was completed as per the protocol outlined above. The participant then donned the safety goggles. The participants could adjust the respirator before applying the safety goggles. QnFT was then repeated, and overall FF was calculated again.

**Statistical Analysis**

Our null hypothesis is that the use of safety goggles does not improve the number of participants who pass the QnFT.

With PortaCount 8048, the numerical data on FF are truncated at the upper bound of 200 (for example, if the FF is greater than 200 in a subject, say 350, it is still reported as 200). The FF is therefore reported as mean  $\pm$  standard error (not standard deviation). As the FF upper limit is truncated, Tobit regression<sup>21</sup> with an upper bound correction (upper limit = 200) was used to analyze this data.

FF  $\geq 100$  was categorized as pass and  $< 100$  as a fail result on QnFT. The pass/fail result is, therefore, “before-and-after intervention” categorical data, which was analyzed using McNemar’s test.

**Ethical Considerations**

The study protocol was approved by the South Eastern Sydney Local Health District Human Research and Ethics Committee. All participants received a participant information sheet and written informed consent was obtained from all participants.

**RESULTS**

**Participant Characteristics**

Sixty-three volunteer HCW participated in the study. The features of the participants are outlined in Table 1. Thirty-five participants were tested using the Halyard FLUIDSHIELD\* 3 Duckbill mask and 28 using the ProShield® Duckbill Mask.

**Fit factor, before and after Application of Safety Goggles**

After the application of safety goggles, the FF increased from 69.4 (SE 8.4) to 169.1 (SE = 14.0). The mean FF increased by 99.7 (SE 14.6) after the application of safety goggles.

An increase in FF was observed in 76.2% of the participants. In 20.6% of the participants, it decreased, while it remained the same in 3.2%.



**Table 2:** Fit factor, before and after intervention

	FF Preintervention	FF Postintervention (with safety goggles)	Change in FF	p value
All participants	69.4 (SE = 8.4)	169.1 (SE = 14.0)	99.7 (SE = 14.6)	$p < 0.0005$
FLUIDSHIELD 3	62.7 (SE = 9.7)	134.4 (SE = 17.9)	71.7 (SE = 17.69)	$p < 0.0005$
ProShield®	77.7 (SE = 14.5)	215.5 (SE = 18.9)	137.8 (SE = 22.5)	$p < 0.0005$

**Table 3:** QnFT pass and FF results for all participants, participants using ProShield® N95 respirators, and participants using Halyard FLUIDSHIELD\* 3 N95 respirators

QnFT pass (i.e., FF >100)	Preintervention n (%)	Postintervention- with safety goggles n (%)	Difference n (%)	Significance
All participants (n = 63)	17 (27)	46 (73)	29 (46)	$p < 0.0001$
ProShield® (n = 28)	9 (32)	26 (93)	17 (61)	$p < 0.0001$
Halyard FLUIDSHIELD* 3 (n = 35)	8 (23)	20 (57)	12 (34)	$p = 0.0018$

**Table 4:** 2 × 2 contingency table for analysis of categorical pass–fail data for all participants

		QnFT result: postintervention (with safety goggles)		Column total
		Pass	Fail	
QnFT result: preintervention	Pass	16	1	17
	Fail	30	16	46
Row total		46	17	63

Of the 126 total FF measurements, the FF was >200 on 32 occasions. These observations were reported as FF = 200. This is the reason for reporting the standard error with the mean instead of standard deviation. Tobit regression analysis showed that the increase in FF with the application of safety goggles was significant, with a mean increase in FF of 99.7 (SE = 14.6),  $p < 0.0005$ .

The FF improved for both the FLUIDSHIELD\* 3 and the ProShield® respirators, as shown in Table 2.

### Overall Respirator Fit—Pass/Fail on QnFT

The number of participants who passed QnFT (i.e., had FF  $\geq 100$ ) increased from 27–73% with the application of safety goggles. In other words, 2.7 times more participants got pass results on QnFT when safety goggles were used. The QnFT results before and after the application of safety goggles are presented in Table 3.

A 2 × 2 contingency table was constructed, as shown in Table 4. Analysis of this binary (pass/fail) data with McNemar's test suggests that the null hypothesis is rejected, and the difference between the two groups is significant, in favor of safety goggles [ $\chi^2$  (1, N = 63) = 27.13,  $p < 0.0001$ , OR = 3 (95% CI = 4.9–1223)]. The result remained significant, in favor of safety goggles, when either mask was analyzed separately—ProShield® (n = 28,  $p < 0.0001$ ) and Halyard FLUIDSHIELD\* 3 (n = 25,  $p = 0.0018$ ).

### Comfort Survey

The results of the comfort survey are displayed in Figure 4. A higher percentage of participants selected Likert scale 4 and 5 responses for almost all questions on the comfort scale when wearing the N95 respirator and safety goggles, indicating that the addition of

goggles to the respirator was less comfortable. When asked how likely they would be to adjust PPE, more participants responded with 4 or 5 when wearing the N95 respirator without goggles. Most importantly, however, when the participants were asked if they would be prepared to wear the respirator and safety goggles together, assuming that the addition of goggles improved fitting of the respirator, and 73% replied: "yes," 22% replied: "maybe" and only 3% of participants replied: "no" (one participant did not respond).

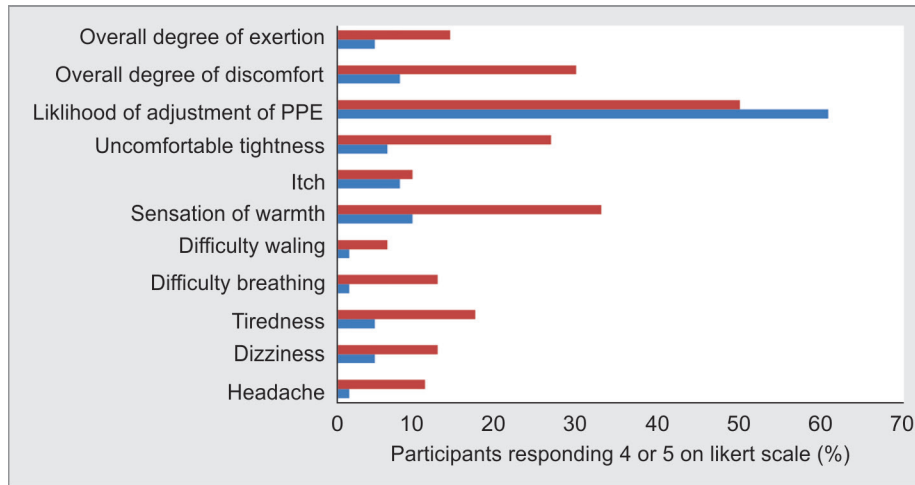
## DISCUSSION

Our study found that the FF of Duckbill N95 respirators increased with the application of safety goggles. In addition, a higher proportion of users passed the QnFT after the addition of safety goggles. We propose that the safety goggles improve the seal of the N95 respirator.

To our knowledge, this is the first study to investigate the impact of safety goggles on the FF of Duckbill N95 respirators.

During the COVID-19 pandemic, HCW have faced a severe shortage of N95 respirators, particularly in developing countries.<sup>1</sup> When supply is limited, HCW may not have access to respirators that fit them well. Limited manpower limits the availability of buddies to help with donning and doffing.<sup>1</sup> In studies where HCW have been formally fit-tested with the respirators available at their workplace, pass rates are highly variable.<sup>22</sup> Any intervention that enhances the safety of the HCW should be thoroughly evaluated and implemented if found useful.<sup>5,14</sup>

The Duckbill N95 respirators are widely available, but several studies have reported a high failure rate on fit testing, like our study.<sup>10,23</sup> Modification of the respirator has been evaluated in some studies. Wardhan et al. conducted the fit test on 26 participants with 3M 1860 and 1860S respirators that had been modified by applying double-sided adhesive tape to the edges of the respirator.<sup>24</sup> Sixty-five percent of participants passed with the modified adhesive respirator. In this study, however, qualitative fit testing was used, which relies on the participant's ability to taste a solution nebulized in the vicinity of the respirator. Qualitative fit testing has a lower sensitivity for the detection of the leak when compared to QnFT.<sup>9</sup> We believe that the use of adhesive tape damages the skin, particularly in the infraorbital region, where it is very delicate. It may also increase the risk of user contamination during doffing of the respirator.



**Fig. 4:** Results of Likert scale comfort survey: percentage of respondents choosing 4 or 5 on Likert scale for respirator alone (blue) and respirator and safety goggles with headband (red)

Our study has a number of strengths. To our knowledge, this is the first study to investigate the role of safety goggles to improve the N95 respirator fit. We used QnFT that employed a protocol approved by the United States Department of Labor Occupational Safety and Health Administration (OSHA 1919.130 protocol).<sup>18</sup> We tested respirators that are widely available and in use in Australia and internationally. Eye protection with goggles is already a part of airborne PPE and is recommended by many institutions like Australia and New Zealand Intensive Care Society.<sup>25</sup> Our intervention serves a dual purpose: providing eye protection and improving the fit of the Duckbill N95 respirator. Finally, our study served an important purpose at the time of the COVID-19 pandemic, which was to complete QnFT with N95 respirators for the staff of our intensive care unit.

We have identified several weaknesses to address. Firstly, our use of a convenience sample, which may limit the external validity of our study. Our participants were relatively young (median age 31 years), majority female (59%); mostly had BMIs in the healthy range (mean BMI 24.7, 13% with BMI >30). Second, we tested only Duckbill respirators. Therefore, the results cannot be extrapolated to any other type of respirator. Third, the same N95 respirator was used for before-and-after intervention testing. The fitting of the respirator may have been altered during the course of the first test. And finally, the assignment of the participants to the two types of Duckbill N95 respirators was not randomized. This was largely due to the availability of the respirators to the investigators. Whilst nonrandomization increases the risk of selection bias, the investigators had little control over which respirator participants were randomized to, as participants were tested with the respirator available in their area of work. Arguably, this reflects a common scenario during the COVID-19 pandemic.

Our results require external validation in users that belong to other demographics, for example, high or low BMI, different races (e.g., Asians), or facial features. Similarly, these results cannot be extrapolated to other mask types, for example, cup-shaped (like 3M 1860) or flat-fold three-panel (like 3M 1870) respirators. A variety of safety goggles are available commercially, some with advanced features like antifog coating. Any deviation from our study group, mask selection, and safety goggle choice requires further evaluation.

Safety goggles with a wraparound elastic headband are widely available and can be thermally disinfected. Eye protection constitutes a mandatory component of airborne PPE.<sup>25</sup> In these times, incorporation of safety goggles to the usual PPE may: (a) result in an increase in the number of employees able to be protected by the available range of N95 respirators, (b) increase the safe use of N95 respirators that are widely available but underutilized due to the fit test failure, and (c) increase the degree of protection for all HCW.

## CONCLUSION

We conclude that the use of safety goggles improves the FF of Duckbill N95 respirators and increases the proportion of users who pass the QnFT.

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