



# 의료용 N95 마스크 밀착도 비교

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## Comparison of N95 Respiratory Mask Fit Testing

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**Background:** In this study, we measured the adherence of the representative N95 respiratory mask products on the current market in Korea, compared, and used the results as reference for selecting masks.

**Methods:** This study was conducted on nurses frequently dealing with patients suspected or diagnosed with airborne diseases at a university hospital in Korea. The fit levels of the three types of masks were measured. A total of 183 people, 48 in product A, 92 in product B, and 43 in product C, participated in the study. The coefficient of adherence to the N95 masks was measured using a quantitative adherence tester (TSI Portcount Pro+8038).

**Results:** Regarding the pass rate of the fit testing, product B showed the highest pass rate in 46 cases (50.0%), followed by 16 cases in product A (33.3%), and one case in product C (2.3%), indicating a significant difference among the products. The overall fit factor of the product was in the order of product B (104.64), product A (82.95), and product C (17.64), which showed that only the overall fit factor of product B was passable.

**Conclusion:** Owing to the difference in fit depending on the type of mask, medical institutions should offer various products; thus, medical service providers can choose an appropriate mask, and regular N95 mask fit testing needs to be mandatory.

**Key Words:** Communicable disease, Masks, Respiratory, Transmission

## Introduction

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which began in China in 2019. COVID-19 has spread rapidly worldwide in March 2020 and has been declared a pandemic by the World Health Organization (WHO). A total of 142,157 people who were infected were also reported in Korea, and 1,968 died of the pandemic (as of March 6, 2021) [1].

Both COVID-19 and Middle East respiratory syndrome

are acute respiratory infections that spread through respiratory secretions [2,3]. Healthcare workers have close and long-term contact with patients who are infected; thus, they should choose and wear appropriate personal protective equipment to avoid infection [4]. In particular, wearing a mask is essential for protection. Masks can be primarily divided into surgical masks and filtering face-piece respirators. Surgical masks have a wide penetration rate of aerosol particles (4-90%) and a wide gap, which poses a risk of many aerosols coming out or inhaling when coughing or sneezing [5,6]. Therefore, it is diffi-



cult to prevent infection with surgical masks in cases of highly contagious acute respiratory infectious diseases [7]. Facial supplementation masks include the N95 respiratory mask in the US, which is equivalent to the KF94 (Korea Filter 94) mask in Korea [8]. “N” of the N95 respiratory mask means “not reserved to oil” and must be used in places without oil mist. The number in N95 or KF94 represents the filtration efficiency of 0.3  $\mu\text{m}$  particles, which are least filtered, the number in N95 or KF94 indicates a 95% filtration efficiency [9]. In Korea, the KF99 and KF94 masks are used to prevent the spread of respiratory infections in healthcare workers [7,8]. The KF99 and KF94 masks have shapes on the ear straps compared with the N95 respiratory masks, which form on the head straps.

The Korea Disease Control and Prevention Agency recommends wearing an N95 respiratory mask or equivalent mask when in contact with patients suspected of or diagnosed with airborne diseases, such as active tuberculosis, avian influenza, pandemic influenza, and others, or when conducting treatments or tests that pose a risk of aerosol, even if they are spread through droplets [10,11]. However, even with a highly efficient filter mask that can reduce the inflow of causative bacteria into the body [12], the contaminated air can be inhaled into the respiratory tract if not adequately adhered to the facial area during work [12,13]. Therefore, before entering the patient’s room with the N95 respiratory mask, health service providers must test the mask by blowing the air hard through the mouth to ensure that the air does not leak out of the mask [10]. Face seal leakage occurs when the mask does not match the wearer’s face, and the Occupational Safety and Health Administration (OSHA) requires medical workers to conduct N95 respiratory mask fit testing before using the mask and after checking the wearer [13]. In Korea, medical staff are also advised to conduct fit testing at least once a year [14], and some medical institutions are conducting fit testing on high-risk medical staff.

Adherence to wearing masks is important in preventing infections. This study measured the adherence of the three representative N95 respiratory masks on the current market in Korea, compared, and used the results as a ref-

erence for mask selection.

## Materials and Methods

### 1. Study design and participants

This study is a descriptive survey that retrospectively analyzed the results of N95 fit testing conducted on nurses working in intensive care units, emergency medical centers, and nationally designated isolation treatment beds at a university hospital in Chungcheongnam-do between August 2018 and October 2020.

The participants were nurses frequently dealing with people with airborne transmission diseases while working in intensive care units, emergency medical centers, and nationally designated isolation treatment beds. During the study period, there were three (A, B, C) masks that underwent fit testing, and the total number of participants who participated in the fit testing was 183 (48 in product A, 92 in product B, and 43 in product C). If a new mask was provided during the study period, N95 mask fit testing was conducted on nurses in the unit; thus, the participants who participated in the fit testing of the three products were not the same.

The researcher explained the protection of personal information and anonymity and conducted a statistical analysis of the collected data.

### 2. Measurements

#### 1) N95 respiratory mask

A total of three N95 respiratory masks that measured adherence were used by the medical staff at the medical institution in the study. Product A (8210, 3M, Minnesota, USA) was a cup-type mask (free size) with an 11-shaped head strap. Product B (N9586727/86827, Halyard Health, Inc., Virginia, USA) was a foldable mask (medium size) with an 11-shape head strap, while the product C (201 N95, Dobu Life TECH Co., Gwangju-si, Korea) was a foldable mask (medium size) with an ear strap.

## 2) Fit testing

For the fit testing device, the PORTACOUNT® PRO+ 8038 Respirator FITster (TSI Inc., Minnesota, USA) was utilized.

## 3) General characteristics

The general characteristics of the participants were examined in terms of gender, age, height, weight, face width, and face length. The face width and length were measured using a sliding caliper, whereas the vertical length from the root of the nose to the tip of the chin was measured in terms of face length [15].

## 3. Procedure

Fit testing was conducted by an experienced infection control nurse who was trained by the manufacturer of the fit testing device on the principles of the device, how to use it, and how to solve problems in the event of a problem. The participants were regularly trained on how to wear the N95 respiratory masks (more than once per year) and also received individual training on how to wear the N95 respiratory masks immediately before the fit testing.

Because the fit testing device measures the facial adherence of the mask by comparing the concentration of fine particles outside the mask, the concentration of fine particles in open spaces may affect the test results [16]. Hence, the fit testing was conducted in enclosed spaces, such as counseling rooms, rather than open spaces, and maintained minimal fine particle concentration during testing with particle generators (Model 8026, TSI Inc., Minnesota, USA) [16]. According to the inspection manual, a disposable N95 respiratory mask filter was installed by penetrating the probe for the device's connection. The location of the probe was such that it was not blocked by the nose and cheeks among the parts for breathing, and the device was connected to the connection probe to conduct fit testing [16].

Fit testing was performed in eight stages in accordance with the criteria of the OSHA quantitative fit testing (QNFT) protocol, and the fit factor passing criterion was

over 100 [16,17]. It was examined in the following order: normal breathing; deep breathing; head movement from side to side; head movement upwards and downwards; speaking; facial frowns; waist bending; and normal breathing. In these steps, facial frowning was significantly different from individual to individual; thus, it was excluded from the test as the fit testing device did not provide any measurements.

The fit factor (FF) was calculated by dividing the concentration of particles outside the mask by the concentration of particles inside the mask using the aerosol method. In this study, the value was obtained using a fit testing device. After performing the step-wise operation, each step coefficient provided by the testing device was checked, and the overall fit factor produced by the testing device was recorded after all stages were completed [16,17].

## 4. Data analysis

Statistical analysis of the data was conducted using the Statistical Package for the Social Sciences (SPSS) 21. Since the normality test showed that the data were not normally distributed, the significance test was carried out using nonparametric statistics. The typical characteristics of the participants were analyzed by frequency, percentage, Kruskal–Wallis test, and Fisher's exact test. The difference in the frequency of the passing fit testing by the product was calculated using the Fisher's exact test. The difference in the fit factor of each product was analyzed using the Kruskal–Wallis test, whereas the post-hoc analysis was carried out using the Scheffé test.

## Results

### 1. General characteristics

Of the total participants, 179 (97.8%) were women, with an average age of 31.50 years. Their average height was 161.27 cm, and the mean weight was 55.34 kg. The average face width and length of the participants were 13.52 and 11.47 cm, respectively. The participants' gen-

eral characteristics are verified for homogeneity, as there are no significant differences among the three groups of products A, B, and C (Table 1).

## 2. The pass rate of the fit testing

Regarding the pass rate of the fit testing, product B showed the highest pass rate in 46 cases (50.0%), followed by 16 cases in product A (33.3%), and one case in product C (2.3%), indicating significant differences among the products ( $\chi^2=29.538$ ,  $P<.001$ ) (Table 2).

## 3. Overall fit factor by products

The overall fit factor of the product was in the order of company B ( $104.64\pm54.36$ ), company A ( $82.95\pm69.38$ ), and company C ( $17.64\pm20.52$ ), indicating significant differences among the products ( $P<.001$ ). Products A and B showed an overall fit factor  $>100$  on average for all phases except for the 7<sup>th</sup> phase, the ‘back bending’ of the fit testing. Among the phases, products A and B had the highest overall fit factor at the second step, the ‘deep breathing’ shown as 134.57 and 151.97, respectively. For product C, the mean overall fit factor for all phases is

$<100$  (Table 3).

## Discussion

This study measured and compared the fit of the N95 respiratory masks used by the medical departments frequently dealing with patients diagnosed with airborne diseases. In the data analysis, product B (foldable mask, parallel hair strap) had the highest pass rate at 50%, followed by product A (dome mask, parallel hair strap) at 33.3%, and product C (foldable mask, ear strap) at 2.3%. Product B had the highest overall fit factor of 104.67

**Table 2.** Number of N95 mask fit test passes (n=183)

	Pass	Fail	$\chi^2$	<i>P</i>
	n (%)			
A (n=48)	16 (33.3)	32 (66.7)	29.538	<.001*
B (n=92)	46 (50.0)	46 (50.0)		
C (n=43)	1 (2.3)	42 (97.7)		
Total	63 (34.4)	120 (65.6)		

A: 8210, 3M, cup/11-shaped rubber band/free, B: N95 86727/86827, Halyard Health, Inc., folding/11-shaped rubber band/medium, C: 201 N95, Dobu Life TECH Co., folding/earring rubber band/medium.

\*Fisher’s exact test.

**Table 1.** General characteristic

Characteristic	Total	A (n=48)	B (n=92)	C (n=43)	$\chi^2$	P
	n (%) / Mean±SD (min-max)					
Sex					1.453	.484 <sup>†</sup>
Male	4 (2.2)	1 (2.1)	3 (3.3)	0 (0.0)		
Female	179 (97.8)	47 (97.9)	89 (96.7)	43 (100.0)		
Age	31.50±8.79 (22.00-57.00)	31.58±8.69 (23.00-50.00)	30.80±8.69 (22.00-57.00)	32.95±9.15 (23.00-50.00)	2.699	.259 <sup>‡</sup>
Height (cm)*	161.27±5.31 (148.00-177.00)	161.90±5.28 (152.00-177.00)	161.25±5.57 (148.00-174.00)	160.62±4.88 (153.00-171.00)	1.346	.510 <sup>‡</sup>
Weight (kg)*	55.34±7.74 (42.00-88.00)	57.59±9.01 (43.00-85.00)	54.44±7.55 (44.00-88.00)	54.63±6.15 (43.00-70.00)	4.978	.083 <sup>‡</sup>
Face width (cm)*	13.52±0.70 (11.20-15.74)	13.65±0.69 (11.74-15.10)	13.39±0.80 (11.20-15.74)	13.60±0.47 (12.50-14.45)	3.754	.153 <sup>‡</sup>
Face length (cm)*	11.47±0.78 (10.44-16.40)	11.45±0.58 (10.45-12.68)	11.48±0.81 (10.44-15.90)	11.48±0.92 (10.56-16.40)	0.348	.840 <sup>‡</sup>

A: 8210, 3M, cup/11-shaped rubber band/free, B: N95 86727/86827, Halyard Health, Inc., folding/11-shaped rubber band/medium, C: 201 N95, Dobu Life TECH Co., folding/earring rubber band/medium.

\*Exclude missing values.

<sup>†</sup>Fisher’s exact test.

<sup>‡</sup>Kruskal–Wallis test.

Table 3. Fit factors of N95 mask

(n=183)

	1	2	3	4	5	7	8	Overall fit factor
	Mean±SD (min-max)							
A <sup>a</sup> (n=48)	130.47±75.08 (0.80-200.00)	134.57±76.67 (0.80-200.00)	115.94±80.96 (1.30-200.00)	101.78±74.81 (1.30-200.00)	123.43±80.03 (1.30-200.00)	74.89±73.85 (2.20-200.00)	112.91±86.69 (2.20-200.00)	82.95±69.38 (1.40-200.00)
B <sup>b</sup> (n=92)	147.27±61.17 (0.40-200.00)	151.97±57.54 (18.00-200.00)	138.72±63.42 (13.00-200.00)	132.92±64.31 (6.30-200.00)	134.08±65.91 (12.00-200.00)	94.37±67.60 (4.20-200.00)	135.74±64.54 (4.60-200.00)	104.67±54.36 (3.30-200.00)
C <sup>c</sup> (n=43)	27.07±34.74 (1.30-200.00)	30.48±37.37 (2.00-200.00)	20.24±24.06 (3.00-200.00)	20.37±28.61 (2.50-200.00)	30.32±42.00 (2.40-200.00)	15.09±16.45 (2.50-200.00)	25.78±43.07 (2.60-200.00)	17.64±20.52 (0.80-200.00)
Total	114.75±78.04 (0.40-200.00)	118.86±77.20 (0.80-200.00)	104.90±78.36 (1.30-200.00)	98.31±75.80 (1.30-200.00)	106.90±77.87 (1.30-200.00)	70.63±69.08 (2.20-200.00)	103.79±80.29 (2.20-200.00)	78.52±63.60 (0.80-200.00)
$\chi^2$	72.69	73.02	79.01	75.24	57.34	57.29	64.86	71.62
P	<.001*	<.001*	<.001*	<.001*	<.001*	<.001*	<.001*	<.001*
	a,b>c	a,b>c	a,b>c	b>a>c	a,b>c	a,b>c	a,b>c	a,b>c

A: 8210, 3M, cup/11-shaped rubber band/free, B: N95 86727/86827, Halyard Health, Inc., folding/11-shaped rubber band/medium, C: 201 N95, Dobu Life TECH Co., folding/earring rubber band/medium.

1: Normal breathing, 2: Deep breathing, 3: Turning head side to side, 4: Moving head up and down, 5: Talking, 7: Bending over, 8: Normal breathing.

\*Kruskal–Wallis test.

<sup>a,b,c</sup>Analyzed by Scheffé test.

(±54.36), followed by A product 82.95 (±69.38) and C product 17.64 (±20.52).

In a study by Bergman et al. [18], the fit of seven types of masks was inspected, and it varied depending on the type of mask. Degesys et al. [19] reported that although their method of evaluating adherence was different from that of this study, the passing rate of fit testing for the dome masks was 72.5%, which was higher than that of the foldable (Duckbill) masks (29.4%). In a study that confirmed the overall fit factor of the masks in Koreans [20], the overall fit factor of foldable masks was higher than that of the dome masks, which was consistent with the present study.

The fit of the mask is influenced by various factors. Byeon et al. [21] confirmed that there are gender differences in the fit of the mask because the size and width of the face affect the fit. In addition, the compositional parts of the mask, such as head straps, nose supports, and staples for fixing the head straps, may also create differences in the fit of the mask. In particular, the shape or elasticity of a head strap may influence the fit, as it is to fix the mask closely to the wearer's face. In the case of product C that showed a very low fit, it is necessary to consider the relationship between the shape and fit of the

mask, as product C uses ear straps, unlike other products. Therefore, it is important to be careful when using an ear strap-type N95 mask when treating high-risk airborne transmission. There was also a difference in the fit of the mask depending on the movement, which in the case of “waist bending,” all three products showed fit coefficients <100. The reason the fit coefficient of the “waist bending” motion is lower than that of other movements is consistent with the results of previous studies [20,22], which is because the adhesion between the nose and the face of the mask decreases owing to the influence of gravity. Therefore, even if one takes care of patients who need airborne precautions after wearing an N95 mask, it is necessary to refrain from bending their waist.

In Korea, the N95 respiratory masks have been used by medical institutions since the influenza epidemic in 2009. It is recommended that N95 masks be inspected for fit testing before use and to be measured regarding the fit level at least once a year [14]. However, inspection is not mandatory. When Middle East Respiratory Syndrome (MERS) was prevalent in Korea in 2015, there were 186 confirmed cases of MERS, and 13.4% (25 persons) were medical personnel [2]. There were cases of infection among the medical staff during the treatment, even



though they were wearing N95 respiratory masks and other personal protective equipment [23]. Therefore, the fit level of the N95 respiratory mask is important, along with whether it is worn, and mandatory fit testing is needed. The participant's facial features can change over time and need to be inspected regularly, not on a one-off basis [24]. In the United States and the United Kingdom, government agencies specifically provide methods, cycles, and precautions for fit testing [24,25]. However, Korea does not yet have official standards for fit testing. Therefore, for accurate fit testing, relevant institutions should establish standards for fit testing methods and cycles.

In the United States, the National Institute for Occupational Safety and Health (NIOSH) bivariate panel checks the size of the wearer's face (width and length) and determines the adequate size of the N95 respiratory mask [17]. However, there are limited types of the N95 respiratory mask on the current market in Korea, and there are not many mask size options available. In addition, the KF99 and KF94 masks in Korea, which are equivalent to N95 respiratory masks, do not have products that provide a standard for selecting masks based on wearers' facial dimensions (width and length). Medical personnel who fail to pass the N95 mask fit testing should be excluded from the task of caring for people with respiratory transmission diseases because it can cause problems in human resource management. Therefore, various types and specifications of the N95 respiratory masks should be provided to enable healthcare workers to adopt and use appropriate products. This will not only reduce the risk of infection among healthcare workers but also contribute to improving work efficiency.

## Conclusion

The worldwide prevalence of COVID-19 is mainly droplet infections, but there is also the possibility of airborne infection when medical institutions perform aerosol-producing procedures, such as endoscopy, sputum induction, endotracheal intubation, and cardiopulmonary resuscitation [3]. In addition, COVID-19 variants increase the probability of airborne infections. It is

essential to wear a mask with a high-efficiency filter that can remove fine particles from the air. If it does not adhere properly to the face, harmful substances may flow into the mask, which may not guarantee the safety of the medical personnel. Owing to the differences in adhesion depending on the types of masks, medical institutions should be equipped with a variety of products to allow each medical worker to choose the appropriate mask and ensure safety through regular fit testing of respiratory protective equipment. The government must clearly offer methods, cycles, precautions, and other relevant measures for accurate inspection.

This study tested the masks that were purchased collectively without considering the face shape of the employees; therefore, caution was needed in interpreting the research results as the study was conducted in domestic situations where various types and sizes of masks were not supplied. In addition, this study conducted a degree of fit testing on one medical institution, and the three mask products created limitations in interpreting the results, as the participants who participated in the fit testing were all different. In this regard, repeated research is required to measure the adhesion between products to the same target, and additional studies on more diverse commercial masks are suggested.

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