Necessity of the Fit Test Panel for Korean Respirator Users: Application to Korean Healthcare Workers

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ABSTRACT

With the recent novel coronavirus disease (COVID-19) outbreak, the importance of respirator fit has been increasing. We attempted to classify the face sizes of Korean Healthcare Workers (HCWs) using the National Institute for Occupational Safety and Health (NIOSH) Bivariate Panel and compared the fit factor by category.

A quantitative fit test was conducted on 56 HCWs from five medical institutions using two types of N95 filtering facepiece respirators manufactured in South Korea. The length and width of the face were measured using calipers. The results of the fit test of the participants categorized using the NIOSH Bivariate Panel were compared among the groups. The face sizes were distributed in and out of the NIOSH Bivariate Panel. There was a significant difference in the distribution of face sizes between our study participants and those in the NIOSH Bivariate Panel ($p=0.009$). The 111 fit test results that we collected did not show a significant difference among the face size categories ($p>0.05$). The pass rates according to the small, medium, large, and outlier categories were not significantly different between the groups ($p=0.767$). Our study has a limitation that it is not representative of all Korean users. Despite this, the difference in face size distribution between the NIOSH Bivariate Panel subjects and Korean HCWs is noteworthy.

There was no difference in the fit test results when the NIOSH facial category was applied, suggesting that applying the NIOSH Bivariate Panel to the face size of Koreans HCWs is not precise. Therefore, it is necessary to develop a Korean test panel and design respirators based on Korean face dimensions. Further, manufacturers should provide varying respirator sizes and styles based on these dimensions to improve respiratory protection for users.

Keywords: coronavirus disease; fit factor; healthcare workers; National Institute for Occupational Safety and Health Bivariate Panel; quantitative fit test

INTRODUCTION

The fit test for respirators is conducted to determine whether the respirator fits tightly enough on the face of the user. The fit test which is used to assess the fit and suitability of the respirator on the wearer, is widely used in medical institutions across South Korea. Considering that a tight-fitting respirator is required when working among patients with new infectious diseases, such as the recent novel coronavirus disease (COVID-19), studies on this aspect have been reported (Kang, 2020; Seo et al., 2020). Several researchers (Han, 1999; Kim et al., 2003) have already evaluated the fit test and test panel for Koreans many years ago; however, a fit test panel for Koreans for regulatory approval has not yet been established.

Han et al., (2017) and Phee et al., (2019) emphasized that it was mandatory to conduct a fit test in the United States (US), United Kingdom (UK), and Australia to prevent the harmful effects of wearing a respirator. Therefore, relevant regulations need to be improved in South Korea for the effective use of respirators. However, several elements must be addressed before implementing the fit test for regulatory approval purposes, one of which is the fit test panel.

In the 1950s and the 1960s, the US collected facial size measurements of military personnel and prepared a fit test panel to determine the design and size of respirators. In the 1970s, the Los Alamos National Laboratory used face length and face width to divide the measurements into 10 face size categories using a bivariate distribution. For full-face and half masks, the face size categories were divided using face length and lip length, respectively. Thus, the fit test panel was developed progressively through numerous National Institute for Occupational Safety and Health (NIOSH) panel research studies (Zhuang & Bradtmiller, 2005; Hack et al., 2005; Hack & McConville, 1978; Zhuang et al., 2007; Zhuang et al., 2008).

The current NIOSH Bivariate Panel divides facial sizes into 10 cells. Such a test panel can be used in the fit test for the initial selection of a respirator that best suits the user group. Chen et al.,(2009) studied whether the NIOSH panel could be applied to Chinese workers, and the results showed that the cell distribution was not uniform and that there were differences within the NIOSH panel for the Chinese and US populations. In the study by Seo et al., (2020) it was found that the face size of Koreans was different from that of the US and Chinese workers, suggesting that a Korean model was required to ensure adequate performance of respirators during the Korean selection process. The guidelines recently published by the National Institute of Food and Drug Safety Evaluation (2020) include performing a fit test to aid in selection, but they do not provide information on the recommended fit test panel.

This study aimed to determine whether there was a difference in the face length and face width of Korean Healthcare Workers (HCWs) from the dimensions given in the NIOSH Bivariate Panel. In addition, we compared the pass rates of the domestic N95 masks to the NIOSH Bivariate Panel.

MATERIALS AND METHODS

Study Subjects

We conducted an experimental study at Shinhan University of Biomedical Laboratory Science, South Korea in 2020. The number of participants was calculated using G-Power 3.1.9.4(Heinrich Heine University, Dusseldorf. Germany) with a significance level of 0.05, power (1-beta error) of 0.9, and effect size of 0.5. In total, 56 HCWs working at five medical institutions in South Korea were recruited. Those participants were randomly recruited in the study.

This study was reviewed by the Institutional Review Board of Shinhan University (IRB; reference No. SHIRB-202006-HR-112-0), and informed consent was obtained from the participants. In addition, personal information was protected and handled anonymously in accordance with IRB regulations. The two types of N95 filtering facepiece respirators used in this study were manufactured in South Korea and certified by NIOSH (Fig. 1). The masks were named mask A (100 × 155 mm foldable type, DOBU MASK Inc., Korea) and mask B (140 × 120 mm cup type, EverGreen Co. Ltd., South Korea). The former included a nose clip, while the latter, which was a cup-shaped model, included a nose clip along with an internal sponge. The mask straps were present in the form of a headband that could be fastened behind the user’s head and neck.

The fit test was conducted by randomizing the measurement order for the two types of masks for each participant. Out of the 112 fit test results, a total of 111 measurements (56 participants x 2 FFRs -1 dropout = 111 Fit tests) were used in this study.

Figure 1. Pictures of the studied FFRs (One size fits all) A: DOBU MASK 201 N95, DOBU LIFE TECH Co., Ltd. Korea, B: Disposable Respirator Clean Top N95 C250, EverGreen Co., Ltd. Korea.

Data on Facial Dimensions

To calculate the face size of the participants, measurements of face length(menton- length) and face width(Bizygomatic breadth) were collected, and the categories in the NIOSH Bivariate Panel were used according to the method of Zhuang et al., (2007;2008). Face length was measured as the distance between the menton and the sellion landmarks, and the face width was measured as the maximum horizontal breadth between the zygomatic arches (Fig. 2). To remove the possibility of variation in the measurement due to different measurers, the two key facial dimensions were measured three times by a single investigator and mean values were recorded. The tools used for measuring the face size were Stainless Steel digital Vernier calipers (HAWK- TZ4512, HAWK Measurement Systems. Medina. Ohio. USA and CD-AX/C, Mitutoyo, Japan) and measurements were taken by an expert researcher with several years of experience in anthropometric surveys with traditional or 3D measurements.

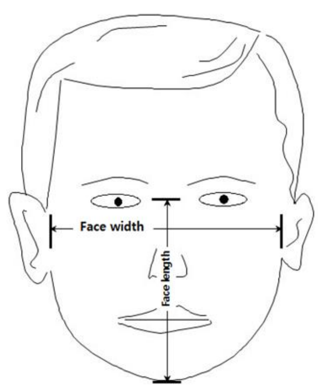

Figure 2. Measured facial dimensions.

Fit Test and NIOSH Bivariate Panel

The HCWs who participated in this study performed the quantitative fit test using Portacount PRO+ 8038 (TSI, USA) while wearing the two types of N95 masks, as follows. He/she conducted the USC (user seal checks) procedures after wearing the respirator for at least 5 min before starting the fit test. For the fit test, the participants performed four exercises from fast Protocol of the Occupational Safety and Health Administration (OSHA), and the overall fit factor was collected for use in the analysis.

The movements included (1) bending over, (2) talking, (3) turning the head from side to side, and (4) moving the head up and down, all of which are indicated under 29 CFR 1910. 134. Appendix A. Fit test is set to take 2 min 29 s. A fit factor of 100 or more, as outlined by the OSHA (2008), was used as the pass value for the test.

The face sizes of the participants were plotted on the NIOSH bivariate fit test panel and compared with the face size category distribution. The NIOSH bivariate fit test panel consisted of 10 cells representing overall subjects' face size. The mentioned cell were classified into three groups. The face sizes of the participants plotted on the NIOSH Bivariate Panel were categorized as small, medium, and large based on whether they fell under cells 1–3, cells 4–7, or cells 8–10, respectively. Eventually, if the overlapping percent between the subjects' facial dimensions and the entirety of the available fit test panel cells computed at least 90%: the NIOSH Bivariate Panel would be considered appropriate to represent the Korean users.

Data Analysis

We analyzed 111 measurements obtained from fit tests. The fit factor showed a lognormal distribution; thus, it was expressed as a geometric mean (GM) and geometric standard deviation (GSD) to evaluate the statistical significance. The fit factor comparison by face size category using the NIOSH Bivariate Panel was analyzed using analysis of variance, and Duncan's (Scheffe) post-hoc test was conducted. The distribution of each face size category of the participants on the NIOSH panel was compared using the chi-square test. The statistical software package SPSS (IBM Corp., Armonk, NY, USA) was used for the statistical analysis of the data. The statistical significance was set at $\alpha=0.05$.

RESULTS

General Characteristics of the Test Participants

Among the 56 participants, 42 (75%) were female and 14 (25%) were male (Table I). This accurately reflected the real proportion of female to male Korean healthcare workers, which was surveyed to be 76% female versus 24% male (Ministry of Health and Welfare 2019).

Table I. General Characteristics of Test Subjects

Classification (N=56)		N (%)*
Sex	Male	14 (25)
	Female	42 (75)
Age	20<	7 (12.5)
	30<	40 (71.5)
	40<	5 (8.9)
	50<	4 (7.1)
Job	Doctor	1 (1.8)
	Nurse	41 (73.2)
	Paramedic	3 (5.4)
	Other (medical technologists etc.)	11 (19.6)

***Number of participants (%)**

As for the age group, those in their 30s accounted for the highest proportion at 71.5% (40 subjects), followed by those in their 20s(12.5%), 40s(8.9%), and 50s(7.1%). Most of the subjects were nurses (41 subjects, 73.2%), followed by other professionals such as medical technologists (11 subjects, 19.6%), paramedics (3 subjects, 5.4%), and doctors(1 subject, 1.8%).

Classification of Facial Size

By plotting the face sizes of 56 participants in the cells of the NIOSH Bivariate Panel, we found that 10.7% (6 subjects), 19.6% (11 subjects), 5.4% (3 subjects), 26.8% (15 subjects), 16.1% (9 subjects), 8.9% (5 subjects), and 1.8% (1 subject) fell under cells 1, 2, 3, 4, 5, 7, and 8, respectively. None of the faces fell under cells 6, 9, and 10 (Table 2). The NIOSH Bivariate Panel was designed such that at least 97.8 % of the population falls under cells 1 to 10 without a blank cell, but the distribution of the face categories in this study was different. While the distribution of face sizes in small-sized cells was 14.4% higher in our study than that in the NIOSH Bivariate Panel, the distributions in medium and large cells were 7.3% and 15.6% lower, respectively (Table II). Furthermore, six subjects (10.7%) were outliers, and their face sizes did not fall under the categories of the NIOSH Bivariate Panel; their face widths were narrower than the smallest size on the NIOSH Bivariate Panel, causing a downward left shift in the plot (Fig. 3).

When Fisher's exact test was conducted, there was a significant difference in the distribution of face sizes between the Korean HCWs in this study and the population used for the NIOSH Bivariate Panel ($p=0.009$). The participants who fell under the small, medium, and large categories accounted for 89.3% of the subjects, which is 8.5% lower than the proportion reported for the NIOSH Bivariate Panel, and 10.7% were outliers who did not fall within the range of the panel.

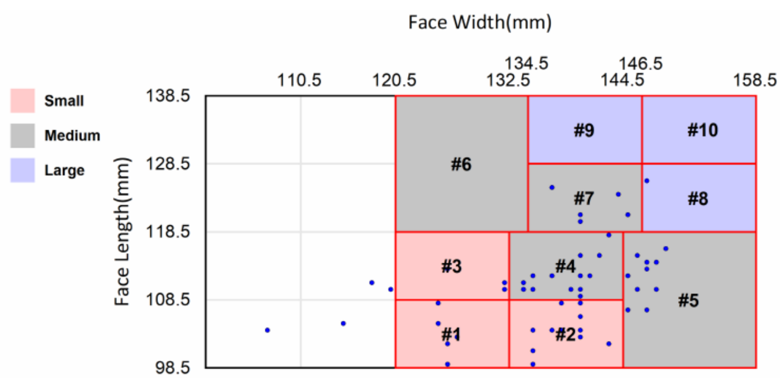

Figure 3. Distribution of study participants in the NIOSH bivariate fit test panel.

Fit Factor by Face Size Category

The mean of the fit factors according to face size is listed in Table III. The highest fit factor was observed for medium size, which showed the highest frequency (51.8%), followed by small size, which had the second-highest frequency (35.7%), and finally the outlier group (10.7%) with a fit factor smaller than that of the small size. The GM(GSD) fit factors for the medium, small, and outlier categories were 25.72 (2.41), 25.51 (4.58), and 22.97 (8.12) for the medium, small, and outlier categories, respectively. There was no significant difference among the face size categories when classified according to the

NIOSH Bivariate Panel (p=0.770). In Table III, descriptive statistics for fit test results obtained from the experimented participants are summarized. 19 females (34.0%) and 10 males (17.8%) belonged to the medium category with the highest fit factor. Six females (10.7%) belonged to the outlier and showed the lowest fit factor.

Table II. Comparison of Face Size with NIOSH Bivariate Fit Test Panel

Cell	Face size category	NIOSH panel†		This study†		P*
1	Small (Cells 1–3)	2(5.5)	6(21.3)	6(10.7)	20(35.7)	0.009
2		2(5.3)		11(19.6)		
3		2(10.5)		3(5.4)		
4	Medium (Cells 4–7)	5(25.0)	13(59.1)	15(26.8)	29(51.8)	
5		2(7.1)		9(16.1)		
6		2(5.7)		0(0.0)		
7		4(21.3)		5(8.9)		
8	Large (Cells 8–10)	2(8.7)	6(17.4)	1(1.8)	1(1.8)	
9		2(5.2)		0(0.0)		
10		2(3.5)		0(0.0)		
total		25(97.8)		50(89.3)	6(10.7)‡	

† Number of subjects in each cell (N), Percentage of the population (%)
‡ represents outliers
P*-value was calculated by Fisher's exact test

Table III. Fit Test Status by Face Size Category

Face size	Subjects		N(%)	FFGM(GSD)	P-value*
	Male	Female			
Small	3(5.4)	17(30.3)	20(35.7)	25.51(4.58)	0.770
Medium	10(17.8)	19(34.0)	29(51.8)	25.72(2.41)	
Large	1(1.8)	0(0.0)	1(1.8)		
Outlier	0(0.0)	6(10.7)	6(10.7)	22.97(8.12)	

GM: Geometric Mean, GSD: Geometric Standard Deviation
*P-value was calculated using ANOVA

Table IV shows a comparison of pass rates by face size for the fit test. The overall pass rate was 51.8%, with at least one pass achieved for 29 participants, and two fails for 27 participants. When the pass rates were compared by face size, the pass rate for the outliers and those in the small size category were 66.7% and 55.0%, respectively. In contrast, the medium face group, which showed the largest distribution with 14 participants, had a pass rate of 48.3% (Table IV). However, there were no significant differences between the participants' face sizes who passed or failed the fit test. The fit test pass rates by face size category as per the NIOSH panel did not show a statistically significant difference (p=0.767).

Interestingly, female participants had higher pass rates than males (41.1 vs. 10.7 %) (Table V). Therefore, the observed difference between the pass rates of female and male in this study was significant(p=0.028). Female participants were mostly distributed in small and medium categories. Also, the t-test showed statistically significant differences between the mean values of the male and female participants' facial dimensions (Table V).

Table IV. Pass Rate for the Face Size Category

Fit test passing rate	N	Pass / Fail	P-value*
Small	20	11(55.0%) / 9(45.0%)	0.767
Medium	29	14(48.3%) / 15(51.7%)	
Large	1	0 (0.0%) / 1(100.0%)	
Outlier	6	4(66.7%) / 2(33.3%)	

Number of subjects in each cell (N), Percentage of the population (%)
*P-value was calculated using Fisher's exact test

Table V. Comparison of Differences by Gender

Differences	Male N=14	Female N=42	P-value*
Mean Face length(mm)	114.8	108.5	<0.05
Mean Face width(mm)	142.7	134.1	
Pass (%)	6(10.7)	23(41.1)	0.028
Fail (%)	8(14.3)	19(33.9)	

Number of subjects in each cell (N), Percentage of the population (%)
*P-value was calculated using t-test

DISCUSSION

When the two types of N95 masks were tested in a total of 56 participants, the face sizes of the participants were distributed in the NIOSH panel with outliers, and there was a significant difference in the face size distribution between our sample and the NIOSH Bivariate Panel sample in that there were a number of small sized outliers, and empty cells in the large portion of the panel.

Wearing a well-fitting mask can be the best option for protecting the respiratory system of HCWs from new infectious diseases such as COVID-19 and other biohazards, as well as for protecting industrial workers from inhalation of dust or hazardous chemicals. In many other countries, there are programs for the selection and management of respirators, and training programs for the correct way to use and wear a respirator are also continuously developed (CSA, 2018; Canada OHSR, 2021). In addition, conducting periodic fit tests is regarded as mandatory (CDCP, 2015; OSHA 2020), but the concept of a fit test or a test panel is still not widespread in South Korea.

Face Size of Korean HCWs Classified Using the NIOSH Test Panel

A study by the National Personal Protective Technology Laboratory (Pittsburgh, Pennsylvania, USA) reported a high fit factor when subjects with small, medium, and large face sizes used small, medium, and large-sized RPEs when respirator size was compared with the fit test results as categorized by the NIOSH panel. However, the pass rate for large face size was only 86%, and although still higher than the pass rates for small and medium sizes, the failure rate was still 14%(Zhuang et al., 2008). Further, the

NIOSH panel could help in designing a respirator with an appropriate size for various face sizes, but there are still problems in passing the fit test; thus, the development of a new test panel is required(Zhuang et al., 2007; Zhuang et al., 2008). Meanwhile, it was suggested that physical characteristics among different ethnic backgrounds could affect the selection of masks, and research was conducted to determine whether the NIOSH panel could be applied to the face size of Chinese workers (Chen et al., 2009; Lin & Chen, 2017); it was found that the NIOSH panel had limited application in Chinese users. Only 6.3% of survey participants fell into five cells of the NIOSH Bivariate Panel (Chen et al., 2009). Therefore, it was reported that the NIOSH panel could not be used because it does not represent Chinese workers. In our study, when the face sizes of the Korean HCWs were plotted directly on the NIOSH Bivariate Panel, the distribution did not match that of the NIOSH Bivariate Panel face size category, and there was a statistically significant difference between the face sizes of the participants and those on the NIOSH Bivariate Panel ($p=0.009$). Based on the NIOSH Bivariate Panel, most of the study participants had medium face size (51.8%) and small greatly exceeded large (35.7% vs. 1.8%). Additionally, 6 (10.7%) of the study participants fell outside of the NIOSH Bivariate Panel.

In particular, 10.7% were outliers, with a face width smaller than the smallest size in the NIOSH Bivariate Panel, and the percentage of faces in the small size category was higher in our subjects than in the NIOSH Bivariate Panel. Overall, there was shift to narrower and shorter faces (Fig. 3). Although the participants were randomly selected in this study, it is possible that many subjects with a small face size were recruited. However, the downward left-shift trend was consistent with the results of the study by Seo et al., (2020) who analyzed the face size of 4,583 Koreans and showed that the face size of Koreans is different from that of the NIOSH Bivariate Panel. Anahita et al., (2020) reported 19.4% of outliers. Additionally, some research conducted in China (Lin & Chen, 2017; Yan et al., 2007) reported a high proportion (12–35%, and 26.2%, respectively) of the participants were outside of the NIOSH fit test panel. In contrast, the other Chinese study performed by Chen et al., (2009) noted that only 5.0% of the subjects were out of the NIOSH Bivariate Panel boundaries. Overall, these findings were consistent with the results of the anthropometric survey by NIOSH showing different face dimensions among different ethnic groups (NPPTL, 2007) and demonstrated the need for constructing a separate panel for Koreans users, as suggested by previous studies which proposed that the test panel should reflect these differences (Seo et al., 2020; Seo et al., 2021).

Difference in Fit Factor Classified according to Face Size Category

In a study by Zhuang et al., (2007; 2008) it was reported that the fit test pass rate by respirator size combined with face size is different for each face size category, and there was a significant difference. Using a small-sized respirator for small face size showed a pass rate of 81% in the fit test and using a medium respirator on a medium-sized face showed a pass rate of 83%. As shown, there was a significant difference in the fit test pass rate for the combination of face sizes classified by the NIOSH panel (Chen et al., 2009) but our results did not show this difference ($p>0.05$). The participants in our study used two N95 filtering facepiece respirators manufactured in one size, and 66.7%, 55.0%, and 48.3% of them in the outlier, small-sized face, and medium-sized face categories respectively, passed the fit test with no significant difference (Table IV). Most of the employers believe erroneously that one-size respirators shall fit all employees. However this study demonstrates that “One size does not fit all,” and it is necessary to provide more than one respirator model, style, and size to achieve the best fit for the full population of users.

One of the possible explanations for these results could be that the size and style of the respirators being tested were not appropriate for the study participants’ facial dimensions. Since this study used domestic N95 filtering facepiece respirators distributed in one size as a test mask, it was not appropriate to compare the passing rate for facial size with those in the studies of Zhuang et al. (2008). As a result of examining the passing rate for each facial size for 51.8% (29 people) of the 56 participants, those were passed with small face 11/20 = 55%, medium face 14/29 = 48.3%, and large face 0/1 = 0. However, four (66.7%) out of the six outliers who did not belong to the NIOSH Bivariate Panel passed the fit test (Fig. 4). Comparing the passing rates by face size (Table 4), it may seem that there were fewer fail cases for the outliers and the participants with large face size than for those with medium face size; however, Fisher's exact test confirmed that there were no significant differences between the participants' face sizes who passed or failed the fit test (p=0.767). However, the face size applied to the NIOSH Bivariate Panel showed a difference in distribution (p=0.009). This could be attributed to the fact that, as shown by Chen et al., (2009) the face size distribution in Chinese and Korean healthcare workers is not similar to that in the NIOSH panel.

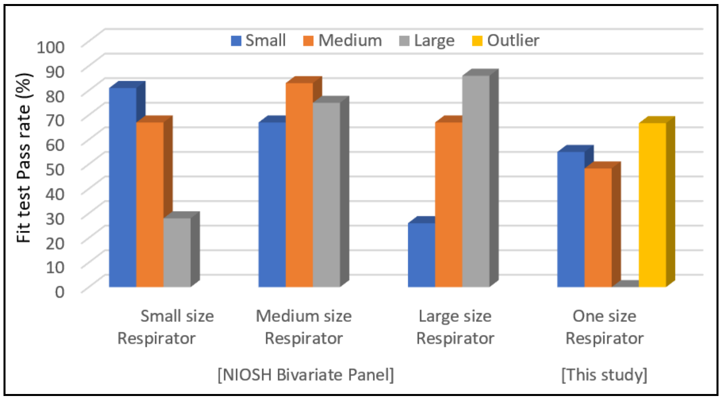

Figure 4. Fit test pass rate by respirator size based on the NIOSH Panel predicted respirator size category.

The NIOSH Bivariate Panel is not appropriate for Korean facial dimensions, which highlights a crucial need to update the comprehensive anthropometric database by measuring the face dimensions of Korean users to develop a specific and optimal fit test panel. Kim et al. (2003) reported that traditional measurements, such as face length and lip length, were not accurate predictors of respirator fit in Koreans. Instead, bizygomatic breadth, menton subnasale length, and biocular breadth were significant predictors (Kim et al., 2003). Although we did not measure these factors in our study, we measured the traditional factors (width and length of the face). These measurements were applied to the NIOSH Bivariate Panel to evaluate respirator fit for Korean users. However, for Korean users, we found subjects' face size, respirator design, and style should all be reflected when evaluating fit.

Limitations

Our study was conducted with HCWs and did not reflect the face size of the general population. The initial version of the NIOSH panel measured the face dimensions of young and healthy US soldiers and constructed a new test panel by expanding the subject pool to include the civilian workforce (Chen, 2009). As shown, constructing a test panel requires a large amount of basic data to be collected, and the data from a standardized population must be extracted to adequately reflect the face size of the users. Therefore, our study population is not representative of all Korean users, which is a study limitation. To establish respirator fit test panels, further studies with a more rigorous and large-scale study design are warranted. Conducting a fit test requires a variety of masks for comparison, but the fact that only two types of domestic N95 masks were used could be regarded as a limitation of this study.
By addressing these limitations and measuring the face sizes for different occupations to collect the fit test data for various types of respirators, the results shall be meaningful as test panel data for Korean respirator users. Thus, it is necessary to conduct a follow-up study based on measurement data from other studies with subjects who could represent the Korean population in order to reflect the facial characteristics of Koreans (Seo et al., 2020).

CONCLUSIONS

The distribution of face sizes of Korean HCWs was significantly different from that represented by the NIOSH Bivariate Panel. Also the fit test pass rate, corresponding to face category classification, did not show a difference by face category. Furthermore, a high proportion of participants (10.7 %) did not fall within the NIOSH Bivariate Panel range. Therefore, the results of the current study demonstrate that the application of the NIOSH Bivariate Panel to Koreans HCWs in a fit test might provide limited evidence for a respirator's capability to fit the HCW population. Currently, experts in the respiratory field in South Korea have expressed the need for a test panel for the fit test, but the actual number of test panel studies conducted to date is insufficient. However, our study provides the basic data for preparing a separate test panel for Korean respirator users, and it is expected that a unique fit test panel can be constructed if the aforementioned limitations are addressed. Follow-up research will help establish a standard Korean face size category and develop an accurate test panel. Meantime, manufacturers need to provide various sizes and styles of the respirators to provide adequate respiratory protection for the users.

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