

Case Study for Verification of the Korean Test Panel Using Fit Testing of Respiratory Protective Equipment

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ABSTRACT

Fit tests determine the adequacy of the seal of respiratory protective equipment. Several researchers (Seo *et al.* 2023; Park *et al.* 2023) have emphasized the necessity of a South Korean fit test panel. A fit test panel is necessary to assess the fit performance of a respirator and its face seal. This criterion is used to select subjects that can represent the facial characteristics of users. Although anthropometric data has been developed for people in the United States and China it is not yet available for Korea. Therefore, we developed the Korean test panel (Seo *et al.* 2023). For the 7th and 8th waves of the Size Korea anthropometry data, facial measurements of 11,429 individuals aged 15 to 69 years were utilized for analysis. The y-axis (face length) boundary was 97.87 to 134.59 mm, while the x-axis (face width) boundary ranged from 120.75 to 158.23 mm. A Total of 10,985 people (96.12%) were included in the bivariate panel based on face length and face width. The face types were classified into three categories. The purpose of this study was to validate the Korean test panel classified using the International Organization for Standardization ISO 16976-2 (2022) method. We recruited forty-five participants that fit this panel and compared the pass rates of fit tests. The pass rate in the small face size category was high when wearing medium-sized respirator. The medium face size category exhibited high pass rate (80%) when wearing medium or large-sized respirator. These results were similar for the large face size category ($p > 0.05$). Finally, the test panel was verified by comparing the face size category and fit test pass rate. The fit test demonstrated good reliability and validity for matching face size categories (Intraclass Correlation Coefficient, ICC 0.532; $p = 0.043$). Therefore, the foundation for a Korean test panel was established. This study conceptualized the standardization of Korean test panels.

Keywords: fit test, ISO, Korean test panel, Size Korea anthropometry, Intraclass Correlation Coefficient

INTRODUCTION

It is essential to select a respirator that fits the user's facial characteristics to provide an effective barrier for workers using respirators. A fit test is used to verify whether the newly selected or regularly used respiratory protective equipment fits the user's face properly. To perform the fit test properly, it is important to match the size of the respiratory protective equipment to the test panel.

The first test panel used previously was the bivariate test panel (Hack & McConville 1978), which was developed using a U.S. Air Force anthropometric survey conducted by the Los Alamos National Laboratory. Thereafter, Zhuang *et al.* (2007) subsequently developed the principal component analysis (PCA) and bivariate test panels for full-face and half-face respirators (NIOSH 2019). Also, bivariate and PCA panels were developed in China (Chen *et al.* 2009). However, since the test panels developed using facial measurement data from these two countries differ from the facial dimensions of Koreans, we aimed to develop a test panel specifically for the Korean population (Seo *et al.* 2020). Recently, test panels can be developed according to standard procedures, with reference to the International Organization for Standardization method in ISO 16976-2 (2022). Several years ago, the relationships between fit factor and facial size of South Koreans were analyzed (Han 2000), and the necessity of a test panel was mentioned. However, the development of the test panel was delayed due to insufficient data on the facial size of the population wearing respiratory protective equipment of South Korea. Thus, there is some ambiguity in determining the accurate fit between commercially available respiratory protective equipment and the user's

face size. Recently, the Korean fit test panel (Seo *et al.* 2023; Park *et al.* 2023) was developed. Currently, fit tests are not mandatory in South Korea; however, if the recently developed Korean test panel is recognized as a standard, it could be utilized in various applications. Therefore, there is a need to validate the newly developed Korean panel using a fit test.

The purpose of this study was to verify whether the Korean test panel is adequate for fit testing. We investigate whether the fit test pass rate varies according to respirator size across small, medium, and large face size categories. The utility of the Korean test panel was verified based on these results. In addition, the results will enable the development of criteria for selection of respiratory protective equipment based on facial size, thereby providing fundamental data for standardizing the Korean test panel.

METHODS

Korean test panel and Fit test

We developed the Korean test panel based on 11,429 subjects from the 7th and 8th Size Korea anthropometric surveys (aged 15–69 years) using ISO methods [5]. The y-axis boundary of the test panel is calculated by adding 2 standard deviations (SD) from the mean male facial length (118.6±8.0 mm) and subtracting 2 SD from the mean female facial length (111.9±7.0 mm). This resulted in a range of 97.9–134.6 mm. The x-axis boundary of the test panel is 120.8–158.2 mm, calculated in the same manner based on the facial width (Table I). With the limits being defined to include over 95% of the population in the panel, 444 (3.9%) out of the 11,429 persons were excluded, and the remaining 10,985 (96.1%) were accepted into the test panel (Table II).

The fit tests were conducted according to the protocol suggested by the U.S. Occupational Safety and Health Administration 29 CFR 1910 (OSHA 2021). The test equipment included a PortaCount 8048 (TSI, USA), and three types of air-purifying particulate respirators certified as KF94. These respirators are filtering facepiece types with a half-face design and ear-loop straps. They are available in three sizes: small, medium, and large. For validation of the Korean test panel, we referenced the NIOSH National Personal Protective Technology Laboratory (NIOSH 2019). For the fit test, the participants performed 4 exercises 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 (OSHA 2021).

Table I. Bivariate measurements based on the Korean face length & width (data from Seo et al., 2023; n=11,429).

	Population Number (%)	Face length / mm Mean ± SD	Face width / mm Mean ± SD
Total	11,429 (100.0)	115.08±8.21	138.34±8.38
Male	5,458 (47.76)	115.59±8.00	142.07±8.08
Female	5,971 (52.24)	111.87±7.00	134.93±7.09
Total bivariate measurement range		97.87-134.59	120.75-158.23

Table II. Classification of the Korean test panel. (Data from Seo *et al.* 2023; of the total 11,429 participants (100%), 444 (3.88%) were excluded).

Cell	Population (n)	Population (%)	Face length (mm)	Face width (mm)
			Mean (SD)	Mean (SD)
1	633	5.54	103.33(2.35)	127.68(3.44)
2	817	7.15	103.19(2.45)	137.41(3.15)
3	1,208	10.57	111.16(2.56)	128.20(3.23)
4	2,662	23.29	111.56(2.56)	138.04(3.32)
5	686	6.00	110.77(3.89)	148.01(2.92)
6	897	7.85	120.06(3.56)	130.60(3.14)
7	2,262	19.79	119.98(2.79)	140.55(3.29)
8	862	7.54	120.84(2.92)	150.48(2.98)
9	503	4.40	128.72(2.51)	141.54(3.23)
10	455	3.98	129.42(2.82)	150.86(3.03)
total	10,985	96.12	115.05(7.67)	138.52(7.65)
	Mean(SD)		114.40(8.03)	137.07(7.12)

*mean(SD) : mm

Study subjects

We recruited participants who fit within the facial length and width criteria outlined in the Korean test panel. These participants were stratified into small, medium, and large face size categories according to the distribution criteria of the Korean test panel, comprising 28.9%, 57.8%, and 13.3% of the total, respectively. Their distribution was similar to that of the Korean test panel population. However, a higher proportion of female participants (71.1%) were recruited compared to the gender distribution of the test panel, which consists of 47.8% males and 52.2% females. We recruited 45 participants through advertisements within the research institution and conducted fit testing after obtaining written consent from them. The participants' general characteristics are shown in Table III. The participants' personal information was protected based on a review by an institutional review board (IRB: SHIRB-202111-HR-142-01).

Table III. General characteristics of the study subjects (n=45).

Category	Range	Number of subjects (% of total)
Age	19-29	39 (86.7)
	30-39	2 (4.4)
	40-49	1 (2.2)
	50≤	3 (6.7)
Gender	male	13 (28.9)
	female	32 (71.1)
Face size category	small (panel 1-3)	13 (28.9)
	medium (panel 4-7)	26 (57.8)
	large (panel 8-10)	6 (13.3)

Data Analysis

All statistical analyses were conducted using SPSS system version 20.0 (IBM Corp., USA). Statistical significance was tested at $\alpha = 0.05$. We utilized descriptive statistics for frequency analysis and conducted post-hoc analysis of variance (ANOVA) tests to investigate the pass rate of the fit test based on face size.

We assessed the reliability of the fit factor based on face size category using the Intraclass Correlation Coefficient (ICC).

RESULTS

General characteristics of the Korean test panel

Using the 7th and 8th surveys of the Size Korea anthropometry data (Seo *et al.* 2023), facial measurements of 11,429 individuals aged 15 to 69 years were utilized for analysis. The y-axis (face length) boundary was 97.87 to 134.59 mm, while the x-axis (face width) boundary was 120.75 to 158.23 mm. 10,985 people (96.12%) were included in the bivariate panel based on face length and face width (Table I). The face types were classified into three categories. The Korean test panel consisted of 10 cells representing overall subjects' face size. The mentioned cells were classified into three groups (small, medium, large) based on whether they fell under cells 1–3, cells 4–7, or cells 8–10, respectively (Figure 1).

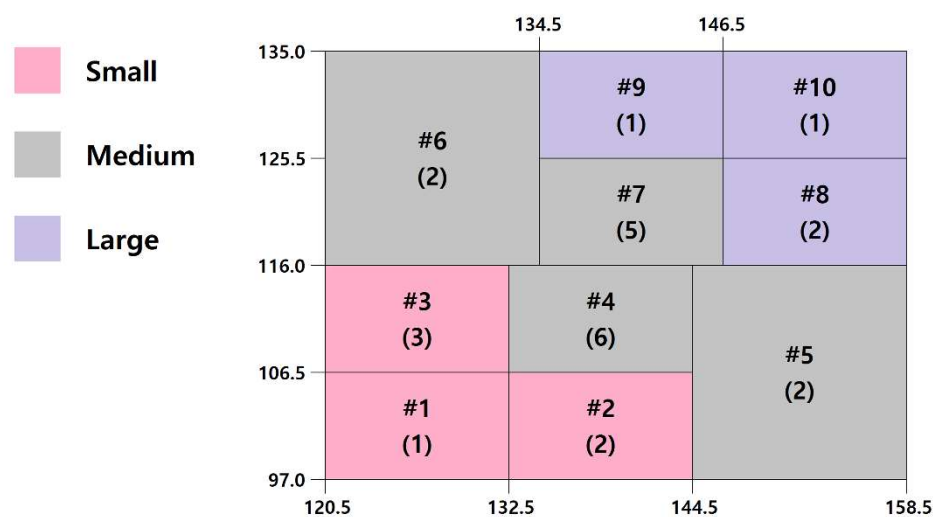


Figure 1. Korean test panel classified by face size category.

Verification for face size category classification

NIOSH test panel cells #1 -10 are categorized into small, medium, and large categories, in a similar manner to the Korean test panel (Figure 1). In addition, the fit test pass rate for respirator size combinations for the large face size category was above NIOSH standards (Zhuang *et al.* 2004)(Table IV). The fit test pass rate was compared across three different respirator sizes for each face size category. The fit test pass rate for the mask size fit test was highest when participants with small faces wore medium-sized respirator. For participants with medium-sized faces, medium and large masks showed the highest pass rates. Participants with large faces also showed a high pass rate when wearing medium and large respirator. The ANOVA analysis revealed significant differences in the pass rates among the three respirator sizes for each face size category. Therefore, a post hoc test was conducted to determine which groups exhibited differences. As a result, although no significant differences were observed ($P > 0.05$), most respirator combinations with high pass rates were consistent with the findings of NPPTL (Zhuang *et al.* 2008), reflecting the trend of the test panel categories.

Figure 2 shows the trends for the fit test after stratifying participants by face size category. Participants with medium and large faces showed the highest pass rates while wearing medium-large respirator. Exceptionally, participants with small faces exhibited lower pass rates when wearing small masks compared to when wearing medium masks. Finally, we validated the test panel by assessing the reliability of the fit

test results. The test pass rate for face size category classification has an intraclass correlation coefficient of 0.532. The Fit test pass rate for respirator size combinations by face size category showed a significantly high correlation. This is considered a “significant” outcome, demonstrating significant validity and reliability ($p=0.043$; see Table V). This demonstrates the potential applicability of Korean test panel for fit tests.

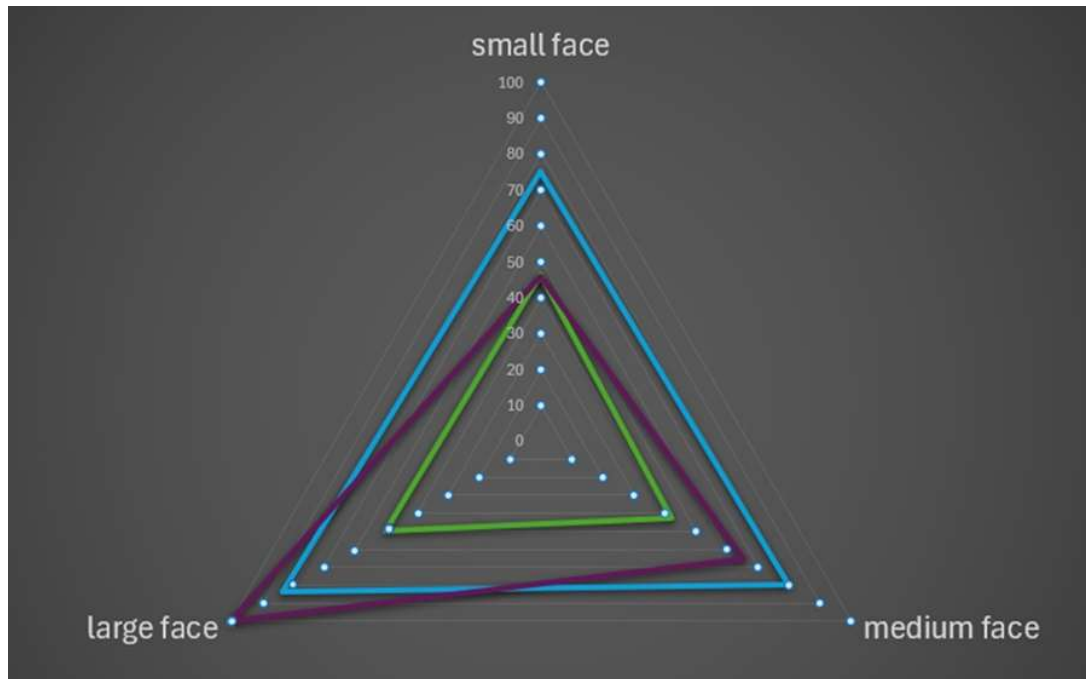


Figure 2. Test pass rate trends by face size category (% pass rate by size of respirator; green: small, blue: medium, purple: large).

Table IV. Comparison of fit test pass rates by face and respirator size.

Face Size Category	Facial dimensions		Passing rate / %			p-value**
	Mean (SD)		Small	Medium	Large	
Small(1-3)	Face length	106.1(3.5)	46.2	75.0	46.1	0.251
	Face width	131.3(4.5)				
Medium(4-7)	Face length	114.4(5.2)	42.3	80.0	65.4	0.089
	Face width	137.1(3.7)				
Large(8-10)	Face length	122.6(4.5)	50.0	83.3	100	0.944
	Face width	142.8(7.6)				

n=135 (45 participants x 3 respirators)

** Duncan's post hoc test

Table V. Reliability of the fit test for face size category.

Cronbach's Alpha	ICC*	95% CI		p**
		lower	upper	
.517	.532	-.112	.830	0.043

*ICC: Intraclass Correlation Coefficient

**p-value was significant

DISCUSSION

Wearing a well-fitting mask can be the best option for preventing the respiratory system of industrial workers from inhaling dust or hazardous chemicals. In many other countries, there are programs for the selection and management of respirators. Training programs for the correct way to use and wear a respirator are also continuously developed (CSA, R2023; Canadian Ministry of Justice 2021). In addition, conducting periodic fit tests is regarded as mandatory (CDC 2015; OSHA 2020). However, the concept of a fit test or a test panel is still not widespread in South Korea. Therefore, we developed the Korean test panel. The Korean test panel, which included 10,985 participants, revealed that 23.6% had small faces, 56.93% had medium faces, and 15.92% had large faces. We recruited forty-five subjects from this panel and compared the pass rates of fit tests. The 45 recruited test subjects showed a similar distribution of 28.9%, 57.8%, and 13.3%, respectively. This distribution differs slightly from the NIOSH panel small (21.3%), medium (59.1%) and large (17.4%) face categories (Seo et al 2021). Therefore, we verified whether the fit test pass rate differed for each mask size based on the face category.

The pass rate in the small face size category was high when wearing medium-sized respirators. The medium face size category exhibited high pass rate when wearing medium or large-sized respirators. In particular, the large face size category had the highest pass rate for fit testing when a large respirator was worn. Finally, the test panel was verified by comparing the face size category and fit test pass rate. The fit test demonstrated good reliability and validity for matching face size categories (ICC 0.532; $p = 0.043$). Therefore, the foundation for a Korean test panel was established. This study conceptualized the standardization of Korean test panels.

In order to provide workers and the general public with effective protection when wearing respiratory protective equipment, it is necessary to formulate standards that can accurately represent the facial characteristics of the users during the testing and manufacturing stages. It is also important to develop test panels that can provide criteria for selecting the appropriate size of protective respiratory equipment. Even if fit tests are performed, the effectiveness of protective equipment may be compromised if the user's face shape and size are not taken into account. This highlights the need for the creation of test panels that accurately represent the target population. Therefore, standards must be established to select a respirator that matches the face size of the users. For decades, many researchers have discussed fit tests and the necessity of a Korean test panel. Studies have indicated that relevant regulations should be enhanced to facilitate the efficient utilization of respiratory protective equipment (Han 1999; Kim *et al.* 2003; Seo *et al.* 2021).

Seo *et al.* (2020) mentioned the necessity of classifying Korean faces due to differences in face size compared to American or Chinese populations. Since the NIOSH panel cannot be adopted for the Korean population without modifications, it cannot be considered to be more useful than a specialized Korean panel. Korean face size tends to be slightly shorter than the standard of the ISO panel and is narrower than that of Chinese people. In other words, Korean faces differed from those in the NIOSH panel and from Chinese faces (Xiao *et al.* 1998; She 2002).

Newly published guidelines by the KFDS (2021) include fit test categories as an assessment method for respirator certification and have conducted several test panel studies (Park *et al.* 2021; Seo *et al.* 2021), highlighting the necessity for a Korean panel. The KFDS (2021) required a fit test before market release to ensure the production of RPEs that properly fit the Korean face. Therefore, a classification system for Korean face sizes was necessary, along with a test panel that allowed for flexible combinations with different respirator sizes. Accordingly, a standardized fit test panel was developed to verify the performance of RPEs for each facial category, enabling more accurate and reliable fit assessments.

The Korean panel developed in this study was designed in accordance with international standards (2022), and meets the criteria for population acceptance rate (96.12%), demonstrating its utility as a Korean test panel. Nevertheless, this Korean test panel has the following characteristics and limitations.

In the case of the NIOSH panel, measurements were expanded to include workers after the initial U.S. military anthropometric survey, and the panel study has been ongoing since (NIOSH 2023). On the other hand, the anthropometric data we used are recent, but they include face length and face width measurements taken while wearing respirator due to the coronavirus pandemic. This process has the disadvantage of potentially introducing measurement bias. To address the limitations of the Korean face length and face width data measured while wearing respirator, more accurate data should be obtained in the future. This indicates that it can serve as a reliable test panel once it incorporates updated anthropometric data.

Moreover, since this study analyzed only a few types of respirator, it may be difficult to generalize the results of test panel validation. In particular, medium and large faces showed a higher fit test pass rate with medium and large RPEs. However, small faces exhibited a higher pass rate with medium-sized RPEs rather than small ones. This suggests the need for further investigation, including a wider variety of RPEs, to determine whether small-sized RPEs are adequate to cover the face sizes of Korean adults. Therefore, it is important to conduct continual follow-up studies to expand the data in accordance with our methodology and explore the possibility of standardization. In this study, we provided foundational data to standardize the Korean test panel and laid the groundwork for establishing validation methods.

CONCLUSIONS

The Korean test panel was classified using the ISO 16976-2 method. We recruited forty-five participants from this panel and compared the pass rates of fit tests. The medium face category exhibited a high pass rate when wearing medium. Likewise, large-faced participants showed a high pass rate when wearing large RPE. These findings mostly correspond with the NPPTL results, reflecting the trend observed when face size aligns with RPE size. Ultimately, it demonstrated good reliability, with an Intraclass correlation coefficient of 53%. However, to establish respirator fit test panels, further studies with a more rigorous and large-scale study design are warranted. In other words, it is essential to conduct separate facial measurements for the population group wearing RPEs. In addition, conducting a fit test requires a variety of RPE for comparison. However, the fact that only three types of KF RPE were used could be considered a limitation of this study. Nevertheless, it is significant that a Korean panel was established using Size Korea data, making the first case of recruiting subjects and validating a Korean panel.

Conflicts of interest

Authors declare that there are no conflicts of interest.

Ethical statement

All study participants provided informed consent, and the study design was approved by the appropriate ethics review board (approval ID: SHIRB 202111-HR-142-01).

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