

Total Inward Leakage (TIL) Testing of Anti-yellow Sand and Quarantine Masks Using NaCl Aerosol

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ABSTRACT

Respiratory protection is dependent on the filtration efficiency and face seal leakage of the respirator. Total inward leakage (TIL) test includes filter's penetration and face seal leakage during wearer's various activities in the fit test. The purpose of this study was to evaluate TIL values using Korean Ministry of Food and Drug Safety (MFDS) test protocol which is adapted from EU protocol. We selected three anti-yellow sand masks and two quarantine masks, which had a high performance in terms of filtration efficiency and pressure drop, and were previously approved by the MFDS or the National Institute for Occupational Safety and Health (NIOSH). For anti-yellow sand masks, the TIL values were significantly higher than the initial filtration efficiency values ($p < 0.0001$). For quarantine masks, the average TIL value was also significantly higher in the TIL test than the initial filtration efficiency ($p < 0.0001$). Facial sizes of test panels have an effect on the TIL values. In the case of anti-yellow sand masks, there were no significant differences in the TIL values among test exercises, and TIL values lower than the MFDS criterion were obtained. The enactment of appropriate standards should be reviewed. The government should also establish the method to select a mask and provide guidelines explaining how to wear the mask correctly.

Keywords: Total inward leakage, anti-yellow sand mask, quarantine mask, MFDS.

INTRODUCTION

The recent increase of yellow sand and its possible association with influenza viruses has raised concerns regarding the health of exposed citizens in Asia and other regions (Kurosaki and Mikami, 2003, Hwang et. al., 2005). Yellow sand dust originates from the arid deserts of China and Mongolia and is known to affect the air quality of China, Korea, Japan, Taiwan, and even North America (Kang et. al., 2004, Zhang et. al., 2010, VanCuren and Cahill, 2002, Chen et. al., 2004, Lee et. al., 2013). Many studies have shown an increase in human mortality, respiratory illnesses, hospitalizations, emergency room visits, and clinic visits following yellow sand dust events (Kang et. al., 2012, Hashizume et. al., 2010, Johnston et. al., 2011, Kim et. al., 2012, Wang et. al., 2014, Yu et. al., 2013, Chan and Ng, 2011).

Influenza also causes annual epidemics of respiratory illness worldwide and is the most important cause of medically attended acute respiratory illness. Moreover, there is increasing concern about the recently declared influenza pandemic due to the 2009 influenza A (H1N1) strain in humans (Loeb et. al., 2009, Langley and Faughnan, 2004).

Many workers use a respirator against solids and/or gases or vapors to protect their respiratory system from respiratory hazards in the workplace (Cho et. al., 2011). Individuals in the general population also use respirators or masks to protect themselves from harmful substances in their external environment. However, respiratory protection is dependent not only on the filtration efficiency of the respirator but also on the face seal leakage. If there are any gaps between the facial skin and respiratory protection devices, regardless of the filtration efficiency, the respirators will not provide appropriate protection to workers or citizens (Lai et. al., 2012). In the worst case, even when an individual is wearing a respirator, they might be exposed to external harmful substances (Zhuang et. al., 2005, Rengasamy and Eimer, 2011, Rengasamy and Eimer, 2012). Therefore, respirator fit testing is desirable before entering hazardous working environments to ensure that the respirator satisfies a minimum fit requirement, and that the user is aware of when the respirator fits properly (Colton et. al., 1991, Viscusi et. al., 2011, Reponen et. al., 2010, Liu et. al., 1993).

For this reason, the fit of a respirator is a crucial determinant of whether adequate respiratory protection is possible. Fit testing is an important factor in protecting the wearer's health (Janssen et. al., 2007, Lee et. al., 2008, Lam et. al., 2011). Several countries and standards organizations have established standardized procedures to assess respirator fit and performance. Fit testing requirements are included in occupational respirator use regulations and standards in the United States, Australia, New Zealand, and Canada (OSHA, 1998, AS&NZ1715, 2009, CSA, 2006). Many European countries, along with Australia and New Zealand, use quantitative fit testing techniques in their certification programs to evaluate the performance of a respirator system (EN136, 1998, EN140, 1998).

Another scale related to respirator fit testing is total inward leakage (TIL) testing. Whereas fit testing examines only whether the fit is good or not, the advantage of a TIL test is that it examines all possible leakages, including filtration efficiency, and facial leakage, both with and without speaking and head motion (WR, 2000).

A test panel is used to determine leakage of a test aerosol from all sources during TIL testing. The panel members actually wear the respirator that is to be used in the workplace. In many European countries, the facial fit is estimated during respirator certification using a TIL test rather than fit testing (EN140, 1998, EN136, 1998).

Unlike respirators for workers, which must be tested and certified by strict standards set by the National Institute for Occupational Safety and Health (NIOSH) in the United States and the Korean Occupational Safety and Health Agency (KOSHA) in Korea, no strict worldwide regulations have been established for TIL testing for masks used by citizens such as anti-yellow sand and quarantine masks.

In Korea, the TIL testing regulations for the certification of particulate filtering respirators used at the workplace are similar to the European Standard (MFDS, 2009, MOEL, 2011). Korean Ministry of Food and Drug Safety (MFDS) recently promulgated regulations on the mask category and performance criteria for masks used by citizens. Anti-yellow sand mask is mainly used to protect particulate matter in the air such as yellow sand dust while quarantine mask is used to protect workers during quarantine task (biocide application), citizens from severe acute respiratory syndrome(SARS) and foot-mouth disease which can cause inflammation of the lungs (Jung et. al. , 2014).

Thus, the test protocols and criteria of anti-yellow sand mask (KF 80) and quarantine mask (KF 94) are different. Filtration efficiency of KF 80 is the same with the European Community's minimum efficiencies for filtering facepiece FFP1 and filter P1 of 80 % and KF 94 with the FFP2 and P2 of 94%. The maximum TIL values for anti-yellow sand mask (KF 80) and quarantine mask (KF 94) are 25%, 11 %, respectively (MFDS, 2009). Limited amounts of data have been published on the effectiveness of these masks, but the numbers of wearers are increasing rapidly and many people are concerned about the efficiency of the protection that is provided.

In previous studies, we evaluated the penetration and pressure drop of various types of respirators used workers (Cho et al., 2011, Cho et al., 2012) or masks used by individuals in the general population (Jung et. al., 2014). It has become necessary to evaluate commercially used masks by using TIL testing. There are many studies of the leakage of particulate respirators for workers (Coffey et. al., 2004, Cooper et. al., 1983, Viscusi et. al., 2009, He et. al., 2013). However, these face seal leakage tests were not human participation tests but relied on mannequin tests or considered only respirators intended for use by workers. The purpose of this study was to evaluate TIL values using the MFDS test protocol, with human test subjects on a panel wearing the anti-yellow sand and quarantine masks, which are commonly used by individuals in the general population.

MATERIALS AND METHODS

Total Inward Leakage Test

We tested 44 brands of masks to ensure that they satisfied the filtration efficiency and pressure drop criteria determined in our previous study (Jung et al., 2014). These masks were selected after visiting several pharmacy stores, searching e-markets on the Internet, and consulting with several health-care workers. Two TSI 8130 Automatic Filter Testers (AFTs) were used for NaCl initial and loading tests, and for paraffin oil quarantine mask initial tests. Initial test was to estimate the value of penetration of the beginning of experiment at ~ 1 minute. These two instruments were designed in compliance with the MFDS protocol and NIOSH Regulation 42 CFR Part 84 protocols, respectively (Jung et. al., 2014). From these masks, we selected a total of five models; three masks were marketed as anti-yellow sand masks and two were quarantine masks. All selected masks displayed a high filtration efficiency and pressure drop, were approved by the MFDS or NIOSH, and were commercially available (Table I).

The MFDS protocol for the TIL test, regardless of facial size, requires a test panel with a minimum of 10 members (MFDS, 2009). Individuals participating in this test should be within the 25-75% quartiles in Korea in terms of facial size. The test panels consisted of ten male and two female volunteers. Males were clean shaven to participate in this study. Four measurements of their face sizes were made: chin to top of nose, ear to ear, ear to end of nose and width of mouth (Han et al., 2004). Measurements were used as the determinants of facial sizes. All measurements were undertaken by one investigator and were made in centimeters to one decimal point using a sliding caliper (No.104, Siber hegner, Switzerland) and spread caliper (No.106, Siber hegner, Switzerland) to reduce measurement biases.

Table I. General Details of Each Type of Mask

Mask No.	Type	Approval and Class		Respirator Material	Shape
		MFDS ^a	NIOSH ^b		
Mask 1	Anti-yellow sand	KF80	N95	Nonwoven	Folded
Mask 8		KF80	N95	Nonwoven	Folded
Mask 9		KF80	-	Nonwoven	Folded
Mask 22	Quarantine	KF94	-	Nonwoven	Cup
Mask 24		KF94	-	Nonwoven	Folded

^a MFDS: Ministry of Food and Drug Safety, which approves anti-yellow sand masks for KF80 and quarantine masks for KF94.

^b NIOSH: National Institute of Occupational Safety and Health in the US, which approves respirators.

The test was conducted at the 3M Korea Innovation Center, in which the experimental instruments and systems for TIL testing were established in compliance with the MFDS protocol and guidelines (similar to the European Standard) for both anti-yellow sand and quarantine masks (MFDS, 2009). Because the TIL test protocol of the MFDS was adopted from an EU protocol, the test instruments used this study were mostly made in the UK, and included an atomizer (Sodium chloride aerosol generator Type 4100250/F, SFP Service, UK), photometer (Model QL30F/RFI, Electron Tubes Ltd., UK) and a pulse sampling unit (Sodium Flame Photometer Type 1150, SFP Service, UK). The photometer output signals were approximately proportional to the aerosol concentration and were used to calculate total inward leakage (TIL) as:

$$\text{TIL}(\%) = C_2/C_1 \times 100$$

where TIL is the total inward leakage, C_1 is the concentration in test chamber (mg/m^3), C_2 is the measured concentration in the respirator of test panel subjects (mg/m^3).

The tests were conducted according to MFDS protocols for TIL, with one exception. The samples were not preconditioned at 38°C and 85% relative humidity (RH) for 24 h prior to testing. This abbreviated test procedure (e.g., no preconditioning) provides results comparable to those obtained from the longer NIOSH certification tests (Rengasamy and Eimer, 2011, Viscusi et. al., 2009). Before the tests were conducted, the panel members adjusted their masks ensure a correct fit. Once they were certain that the mask was in place correctly, the test was conducted. For some panel members it was necessary to readjust their masks several times. Each panel tested all five masks individually. Five test periods were conducted, each lasting for 2 min. Each panel member tested the masks according to the following sequence: walking with normal breathing, turning their head from side to side, up and down movement of their head, and talking and walking with normal breathing. This test was performed on a treadmill at a speed of 6 km/h and was repeated three times.

Before the TIL test, a zero calibration was performed and the test aerosols were confirmed to meet the size criteria of the MFDS using a scanning mobility particle sizer (SMPS: TSI-3910, TSI Inc., Shoreview, MN, USA).

Statistical Analysis

All TIL data were analyzed using the arithmetic mean value according to the European standard for respirators (EN136, 1998, EN140, 1998). ANOVA tests were performed on TIL values according to the type of mask, differences in the initial penetration and the TIL values of the test mask, differences in the

TIL values among test panel members and differences in the TIL values recorded for the different exercises performed in each test. To compare the anti-yellow sand and quarantine mask types, we used a paired t-test. All analyses were performed using SAS for Windows 9.3 (SAS Institute Inc., Cary, NC, USA) at $\alpha = 0.05$.

RESULTS

Particle Size Distribution of the NaCl Aerosol

Figure 1 shows the size distribution of the NaCl aerosol particles measured by an SMPS. The average count median diameter (CMD) and geometric standard deviation (GSD) of the NaCl aerosol were 98.3 nm and 2.19, respectively, which were somewhat larger than the CMD used for filtration efficiency test before (Jung et al., 2014) and NIOSH criteria (CMD, 75 ± 20 nm, GSD, 1.86) of test aerosol for non-powered air purifying respirator efficiency. The MFDS protocol requires a test aerosol concentration to be within 8 ± 6 mg/m³, the particle size range to be within 0.02-2 μ m and the average diameter to be 0.6 μ m. In our study the average aerosol concentration and particle size range were matched with the MFDS criteria, but the average particle diameter was not directly comparable. The MFDS guidelines for the testing of anti-yellow sand and quarantine masks are ambiguous with regard to average particle diameter. They do not define whether the average particle diameter is the count median diameter (CMD) or the mass median diameter (MMD), and state only the average particle diameter.

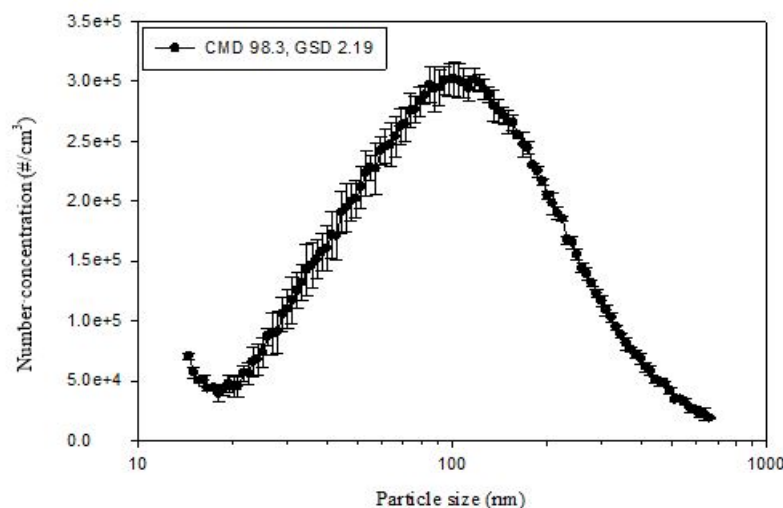


Figure 1. Number concentration of NaCl aerosols used in the MFDS protocol as measured by a scanning mobility particle sizer (SMPS).

Total Inward Leakage

We measured four facial dimensions of test panels. The average values of chin to top of nose, ear to ear, ear to end of nose and width of mouth are 11.72cm, 14.52cm, 11.44cm, 5.43cm, respectively. We evaluated the filtration efficiency in a previous study (Jung et. al., 2014). Table II shows the comparison of initial filtration efficiency and the TIL values for each mask. The MFDS has an initial filtration efficiency criterion for anti-yellow sand masks of 20% (KF 80) and for quarantine masks of 6% (KF 94). A TIL criterion also exists for anti-yellow sand and quarantine masks with TILs of 25% (KF 80) and 11% (KF 94), respectively. For anti-yellow sand masks, the average initial filtration efficiency and the TIL values were $1.1 \pm 0.2\%$ and $2.9 \pm 5.4\%$, respectively. For anti-yellow sand masks, the total inward

leakage values were significantly higher in the TIL test than the initial filtration efficiency ($p < 0.0001$). For quarantine masks, the average initial filtration efficiency and the TIL value of quarantine mask were $0.9 \pm 0.1\%$ and $11.6 \pm 17.2\%$, respectively, and the total inward leakage values were significantly higher in the TIL test than the initial filtration efficiency ($p < 0.0001$).

Quarantine mask 24 satisfied the MFDS quarantine mask criterion with an 11% TIL value (KF 94). However, quarantine mask 22 exceeded the limit value with a TIL value that was twofold the TIL criterion. Mask 22 provided a less efficient seal between the facial skin and mask.

Table II. Comparison of the Arithmetic Means of the Initial Filtration Efficiency and TIL Values by Mask Type

Mask Classification		Initial Filtration Efficiency (%)			TIL Values (%)			P value *	P value **
		Mean	±	SD	Mean	±	SD		
Anti-yellow sand	Mask 1	1.6	±	0.1	4.4	±	6.2	< 0.0001	
	Mask 8	1.2	±	0.3	0.7	±	1.0		
	Mask 9	0.6	±	0.2	3.6	±	6.4		
	Total	1.1	±	0.2	2.9	±	5.4		< 0.0001
Quarantine	Mask 22	1.1	±	0.1	22.4	±	19.0	< 0.0001	
	Mask 24	0.8	±	0.1	1.8	±	5.7		
	Total	0.9	±	0.1	11.6	±	17.2		

*The difference in test results between the initial filtration efficiency value and total inward leakage within each mask type.

**The difference in test results between the initial filtration efficiency value and total inward leakage of anti-yellow sand masks and quarantine masks.

Table III shows the minimum and maximum leakage values for the various mask types. There were marked differences between the minimum and maximum leakage values. For example, there was a 342-fold difference between the minimum and maximum leakage values of quarantine mask 24. The minimum TIL values (0.3% for mask 22 and 0.2% for the other four masks) satisfy the MFDS criterion for TIL and are negligible. In contrast, most of the maximum leakages were very large, and far exceeded the MFDS criterion. All of the masks tested displayed higher TIL values than the MFDS criterion, with the exception of mask 8.

The TIL values for different test panels are summarized in Table IV. The results showed a wide variation between panels. All anti-yellow sand masks and quarantine mask 24 satisfied the KF 80 and KF 94 criteria for all test panels. However, 7 of 11 panels (64%) failed to meet the TIL criteria of 11% for quarantine mask 22, with TIL values fluctuating among test panels. For example, the TIL value of test panel 10 was 47.9% while it was 3.2% in test panel 5, a 15-fold difference. When conducted the leakage test between the different test masks were shown significantly different TIL values of all test masks. (For masks 1, 8, 9, and 22, $p < 0.0001$; for mask 24, $p = 0.0093$).

Table III. Maximum and Minimum Arithmetic TIL Values According to Mask Type

Mask Classification		TIL Values (%)					
		KF 80			KF 94		
		Max.*	Min.**	Max./Min.	Max.*	Min.**	Max./Min.
Anti-yellow sand	Mask 1	28.3	0.2	141.5			
	Mask 8	9.0	0.2	45.0			
	Mask 9	45.8	0.2	229.0			
	Total	27.7	0.2	138.5			
Quarantine	Mask 22				76.1	0.3	253.7
	Mask 24				68.5	0.2	342.5
	Total				72.3	0.2	361.5

* Maximum value of TIL.

** Minimum value of TIL.

Table IV. Mean TIL Value among Test Panels for Each Mask

Test Panel (No.)	TIL values (%)				
	Anti-yellow sand mask			Quarantine mask	
	Mask 1	Mask 8	Mask 9	Mask 22	Mask 24
1	1.6	1.8	13.0	39.3	8.0
2	2.1	0.5	4.7	14.8	0.6
3	0.6	0.4	0.4	3.8	0.4
4	1.8	0.4	0.6	32.9	1.0
5	0.4	0.3	0.4	3.2	0.4
6	7.3	0.3	4.0	36.5	2.9
7	7.4	0.7	0.4	27.4	0.4
8	5.9	0.5	2.3	10.4	0.4
9	1.4	0.4	0.5	*	0.6
10	6.0	1.8	2.2	47.9	3.1
11	3.6	0.5	0.5	10.1	1.6
12	14.6	0.4	13.7	19.8	1.6
P value **	<0.0001	<0.0001	<0.0001	<0.0001	0.0093

* Data were lost by the researcher.

** The difference in TIL values among test panels for each mask tested.

Table V shows a comparison of each exercise performed during the TIL test. For anti-yellow sand masks, there were no significant differences in TIL values among the test exercises and all had lower TIL values than the MFDS criterion. Quarantine masks also displayed no significant differences in TIL values among the test exercises. However, quarantine masks did not satisfy the MFDS criterion of 11% (KF 94). Quarantine mask 22 in particular did not satisfy the MFDS criterion and produced considerable leakage ($26.5 \pm 20.7\%$) during up and down head movements.

Table V. TIL Values for Each Test Exercise Performed

Mask Classification		TIL values (%)					P value
		First Normal breathing	Turning head side to side	Moving head up and down	Talking	Last Normal breathing	
		Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	
Anti-yellow sand	Mask 1	3.2 ± 4.9	3.9 ± 6.5	4.4 ± 6.3	4.2 ± 5.0	6.2 ± 7.5	<0.0001
	Mask 8	0.4 ± 0.1	0.4 ± 0.2	1.0 ± 1.7	0.9 ± 0.6	0.8 ± 1.1	<0.0001
	Mask 9	2.5 ± 4.1	4.1 ± 6.2	3.6 ± 5.3	2.8 ± 5.3	4.7 ± 9.7	<0.0001
Quarantine	Mask 22	19.4 ± 17.1	23.8 ± 20.5	26.5 ± 20.7	19.1 ± 16.7	23.1 ± 19.8	<0.0001
	Mask 24	0.9 ± 0.9	1.5 ± 3.1	1.8 ± 3.3	1.5 ± 3.5	3.2 ± 11.5	<0.0001

DISCUSSION

The aim of this study was to use the MFDS test protocol to evaluate the TIL values of anti-yellow sand masks and quarantine masks, which are used widely by the general population. We found that the initial filtration efficiency and TIL values were significantly different ($p < 0.0001$). The TIL values for anti-yellow sand masks were significantly different from the TIL values for quarantine masks ($p < 0.0001$). For anti-yellow sand masks, mask 8 had the minimum TIL value of $0.7 \pm 1.0\%$ and mask 1 had the maximum leakage of $4.4 \pm 6.2\%$. However, all of the anti-yellow sand masks tested satisfied the MFDS TIL criterion. However, for quarantine mask 22, the filtration efficiency of $1.1 \pm 0.1\%$ was less than the 6% failing to meet the MFDS initial filtration efficiency criterion (KF 94). The TIL values of mask 22 were more than two-folds that required by the MFDS TIL criterion. These results were caused by the nose clip on mask 22 that was designed to help the mask stick closely to a face; however, it was composed of a rigid material and did not fit well the noses of panel members. The lack of effective cover near the nose area resulted in considerable leakage and made it difficult to place the mask close to the face of the wearer. A previous study calculated the dimensions of the contact area between a one-size N95 respirator and a variety of headforms: small, short/wide, medium, long/narrow, and large. The study also measured many different sites on the head, including the upper nose, left nose, and right nose. These measurements were designed to identify the size of the contact area between the respirator and various locations on the head for a variety of headforms. The contact area between the respirator and the head was greater for larger headforms. These results suggest that the contact area around the nose has an important function in providing protection (Lei et. al., 2014). Oestenstad and Bartolucci (2010) also used test panels to conclude that the largest leaks occurred at the nose and cheek. This suggests that an effective seal around the nose area could reduce leakage from face masks considerably. Therefore, if individuals in the general population use a respirator or face mask, it is important that they select a respirator that is securely sealed on all sides of the face, particularly around the nose.

Table III shows the minimum and maximum leakage values as well as the ratio of minimum to maximum values for the various masks tested. Han and Lee (2005) reported that when penetration through the filter medium is large, the minimum leakage would also be large and the ratio of the minimum to maximum leakage would be small. Therefore, if a mask is fitted well, the penetration through the filter medium to the face of the wearer will be negligible. This result indicates that while penetration through the filter medium may be insignificant, leakages can be mostly attributed to face seal leaks (Han and Lee, 2005). In our study, the maximum TIL values of quarantine masks were 254- (mask 22) and 350- (mask 24) fold higher than the minimum values, and the corresponding values for anti-yellow sand masks were 142- (mask 1), 45- (mask 8), and 22- (mask 9) fold increases. The ratios of the minimum and maximum leakage values for the masks were similar to previous studies. If both minimal TIL value and the ratio of minimum and maximum TIL values are low, the mask is well-fitted to the face and provides a good level of protection. The minimum TIL values satisfied the MFDS criterion for TIL; moreover, all values were negligible. However, the maximum TIL values were considerably higher than specified by the criterion. Table 4 shows a comparison of the results from the test panels for the various mask types. The TIL values differed significantly among test panels for all masks ($p < 0.0001$). Before the experiment, members of the test panels were instructed on how to wear a mask correctly and how to undertake the test exercise with a supervisor. Van der Sande et. al. (2008) investigated filtration efficiency and fit using a tea cloth mask, surgical mask, and an FFP2 mask, which can be easily used by the general population during a pandemic. The results of their study indicate that, regardless of mask type, children would be significantly less protected from exposure to external substances than adults, due to the inferior fit of the masks on a smaller face. Therefore, a variety of test panels, containing individuals with a variety of facial sizes, should be used to certify the performance of masks of various sizes.

Table IV shows the TIL values from the test panels. The test panels that produced the minimum value included panelists in whom the jaw to philtrum length was less than those of the other panels. The test panels that produced the maximum value included panelists in whom the ear to nose length was larger than those of the other test panels. The lengths of the jaw to the philtrum and the ear to nose affect the facial leakage rate (data not shown). Oestenstad and Bartolucci (2010) undertook a categorical analysis and found that face seal leakage was significantly associated with the position and facial shape of test panel members.

It is commonly assumed that the size and position of face seal leaks change constantly during actions such as breathing, talking, and head/body movement (Han, 2000, Myers et. al., 1996). Several studies have evaluated respirators worn by human subjects performing such activities. One study involving three half-masks and 10 FFRs that were tested on a panel of 10 human subjects concluded that the performance of elastomeric half-masks was better than that of FFRs (Han and Lee, 2005). Lawrence et. al. (2006) conducted a study involving a panel of 25 subjects with varying face sizes and reported the superior performance of elastomeric N95 half-masks (15 models tested) compared to N95 FFRs (15 models tested) and surgical masks (6 models tested). However, the relevance of these findings is limited to respirators intended for use by those in specific workplaces, such as a hospital, or specialist laboratories that handle small particle sizes (e.g., nano particles) (Rengasamy and Eimer, 2011, Shaffer and Rengasamy, 2009, Lam et. al., 2011, Derrick and Gomersall, 2005).

Despite having a high filtration efficiency, quarantine masks displayed more highly variable TIL values than anti-yellow sand masks. As seen in Table 5, when the test panel performed the final normal breathing exercise, the overall TIL value was higher than for the other test exercises. The total inward leakage test was performed while running on a treadmill at 6 km/h, and resulted in a greater breathing burden and more leakage. For the anti-yellow sand mask, the highest leakage value was recorded in the normal breathing test exercise during the final stage. This was due to the relatively good adhesion with no space between the face and mask, rather than the design of the quarantine mask. Vigorous exercise can result in rough breathing, which can generate more leakage.

If a mask is fitted well, the wearer's face penetration through filter media will be very little. This result indicates that while penetration through filter media may be insignificant, leakages would be mostly attributed to face seal leaks (Han and Lee, 2005). A high efficiency and low pressure drop is important to ensure an effective and comfort mask. When wearing a mask that does not fit well, hazardous substances in the external environment may bypass the filter. Therefore, when designing a facial mask, the facial fit is another important parameter. To decrease TIL values, development of a well-fitting mask or respirator is a greater priority than development of a high-efficiency filter. The wearer should also become familiarized with the correct way to wear a mask to protect themselves.

The TIL results in this study indicated that one of the quarantine masks did not fit well to the facial skin, and the anti-yellow sand masks had the lowest TIL values. Although quarantine masks have a high filtration efficiency, anti-yellow sand masks are less costly and more readily available than quarantine masks. Therefore, individuals in the general population use anti-yellow sand masks more often than they do quarantine masks. Therefore, MFDS should introduce a quality control system and reconsider the test protocol for anti-yellow sand masks, quarantine masks, and other types of mask that are used by the general population in Korea.

CONCLUSIONS

Five different brands of anti-yellow sand masks and quarantine masks were evaluated using the MFDS (similar to EU protocol) TIL test protocol. Most of the anti-yellow sand masks and quarantine masks tested satisfied the maximum TIL criterion of 25% (KF 80) and 11% (KF 94), respectively. Quarantine mask 22 was an exception, in that the maximum TIL values were 350-fold higher than the minimum TIL values. A wide variation in TIL values among the test panels ($p < 0.0001$) was evident due to the variety of facial dimensions of the members and the uniform size of the masks tested. The standards of masks worn by the general population, including health care workers, should be reviewed. The government also should establish the reasons that a mask should be worn and provide clear guidelines regarding how to wear the mask correctly.

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